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Medicare

Renal Dialysis Facility Manual

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FOREWORD

I. Introduction

This manual is intended for use by nonhospital operated renal dialysis facilities, which were included in references to "limited care facilities" in interim program instructions. These facilities may be located on or off the hospital (provider) premises and are engaged in furnishing maintenance dialysis services to established patients. In those instances were a nonhospital operated renal dialysis facility is located on the hospital premises, the administration of the facility must be separate from that of the hospital. Medicare approved nonhospital operated facilities are assigned identification numbers within the range of 2500-2599. Approved renal dialysis facilities that are hospital operated must use the instructions that are included in the Medicare Hospital Manual (HIM-10), rather than these instructions.

II. Function of Renal Dialysis Facility Manual

This manual contains a consolidation of all instructions necessary for properly submitting renal dialysis bills for services to Medicare patients. In addition, since patients often look to their treatment facility for general information about Medicare or for Medicare coverage rules for services that may only be furnished by transplant hospitals, general information has been included so that you may respond to such general inquiries. More detailed information is available from the Medicare fiscal intermediary, the local social security office, or the nearest Bureau of Health Insurance Regional Office.

III. Organization

An overall table of contents appears at the front of this manual. In addition, a partial table of contents precedes each of the four chapters. The four chapters are:

Chapter One - General information about Medicare coverage, financing, and administration;

Chapter Two - Covered services and supplies usually involved in treating patients with kidney disease;

Chapter Three - Instructions for properly submitting bills and medical information;

Chapter Four - Reimbursement rules and information affecting allowable charges for renal dialysis services.

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IV. Renal Dialysis Facility Manual Revisions

The manual is designed to accommodate new pages as further interpretations of the law and changes in policy and procedures are made. Accordingly, supplements and revised sections, pages, or chapters are issued as the need presents itself. Changed material is indicated in the left margin of a page in the following manner:

⌜ Line on which change begins

⌞ Line on which change ends

The revision transmittal sheet identifies new page numbers and the pages replaced, and summarizes the principal changes in the material being issued. When a major change in policy or procedures is involved, the background and effective date for the change is provided. If, at a later date, you wish to refer to the background explanation given on a transmittal sheet, you can identify the transmittal by its number which appears on each manual page.

V. Use of the Revision Transmittal Check Sheet

Immediately after the title page, a check sheet has been provided on which receipt of revisions can be recorded. Revised manual transmittals should be filed in transmittal number order to avoid discarding a more recent page in favor of an older one.

If it appears that you have been skipped in the distribution of a particular transmittal, keep in mind that the transmittals are not always distributed in strict numerical sequence. Allow 10 working days after receipt of a higher numbered transmittal before requesting a transmittal that you have not received.

VI. Supplementary Instructions

The Renal Dialysis Facility Manual system provides for the issuance of supplements which permit speedy communication of information and instructions when legislation is enacted amending the Social Security Act. Supplementary instructions are distinguished by the letter prefix to the section number, e.g., A201, and when feasible, by the use of colored paper. These supplements are filed at the end of each chapter for ease of reference. As soon as practicable after issuance, supplement materials will be incorporated into the permanent manual text.

VII. Intermediary as Information Source

Your intermediary will answer any questions you may have about Medicare policies and procedures. Facilities dealing directly with the Social Security Administration may direct questions to the Regional Medicare Director for reply or refer them to the Provider Liaison and Appeals Branch of the Division of Direct Reimbursement.

Non-Hospital Renal Dialysis Facility Manual

Use this check list to record receipt of revision transmittals.

Trans. No.	Date	Trans. No.	Date	Trans. No.	Date	Trans. No.	Date
1	6/77	21	4/85	41		61	
2	10/19/77	22	5/85	42		62	
3	11/10/77	23	5/85	43		63	
4	11-24-78	24	2/86	44		64	
5	11-24-78	25	3/86	45		65	
6		26	9/84	46		66	
7		27	9/87	47		67	
8		28	11/87	48		68	
9	6/2/81	29	9/87	49		69	
10	6/2/81	30	12/87	50		70	
11	6/2/81	31	3/87	51		71	
12	9/1/82	32	5/87	52		72	
13	7/	33	5/87	53		73	
14	1/25/83	34	6/88	54		74	
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100. INTRODUCTION

Medicare is a health insurance program for people 65 and older and for some people under age 65 who are disabled or have end stage renal disease. The Medicare provisions are in Title XVIII of the Social Security Act under the heading, "Health Insurance for the Aged and Disabled." Medicare has two parts, Hospital Insurance (sometimes called Part A or HI) and Supplementary Medical Insurance (Part B or SMI). Facilities that use this manual provide services only under Part B.

The effective date of Medicare coverage for almost all persons 65 and over is the month of their 65th birthday. Since July 1973 Medicare also has been available to persons of any age who are entitled to disability benefits under the Social Security Act or Railroad Retirement Act for a specified length of time. Persons entitled to disability benefits under the Social Security Act for 24 consecutive months are entitled to HI beginning with the 25th month of entitlement and are automatically enrolled in the supplementary medical insurance (SMI), unless this coverage is refused. HI and SMI for beneficiaries under age 65 who qualify under this provision will terminate the month the disability benefits terminate or the month following the month a notice of disability termination is mailed to them, whichever is later.

Also, since July 1973, persons under age 65 who do not meet the above disability requirements but need dialysis or renal transplantation for treatment of end stage renal disease are eligible for HI or SMI under certain conditions (see § 105.3).

102. HOSPITAL INSURANCE (PART A)

Medicare's Hospital Insurance helps pay for medically necessary inpatient hospital care, and, after a hospital stay, for inpatient care in a skilled nursing facility and for care at home by a home health agency.

Persons covered by social security (and their employers) pay tax contributions into a special Hospital Insurance Trust Fund during their working years to insure them against the costs of illness in their older years or in a period of disability. Persons age 65 and over who meet certain residence requirements but are not otherwise eligible for Part A benefits may pay premiums to obtain such coverage if they already have SMI coverage or are eligible for SMI enrollment and file a timely enrollment request.

104. SUPPLEMENTARY MEDICAL INSURANCE (PART B)
SMI is a voluntary program which builds upon the protection provided by the basic hospital insurance plan by covering a substantial part of the cost of physicians' services (including surgery), maintenance dialysis treatments, and a number of other health items and services not covered under Hospital Insurance. SMI is financed through premiums paid by each person who enrolls and through contributions from Federal general revenues which are at least equal to the amount of premiums paid by beneficiaries.

Medicare Entitlement

105. HOSPITAL INSURANCE

105.1 Hospital Insurance for the Aged.--An individual is entitled to hospital insurance (HI) beginning with the first day of the month he attains age 65 if he had applied for and been determined to be entitled to monthly social security benefits. It is not necessary to be retired and actually receiving the monthly benefit payments. Entitlement also extends to qualified railroad retirement beneficiaries. (For social security purposes, a person attains age 65 on the day before his 65th birthday. Example: If his birth date is August 1, his attainment date is July 31, and HI entitlement date is July 1.)

A social security applicant who applies for monthly benefits after he attains age 65 is entitled to HI coverage retroactive to the first month in which he attained age 65 and met all the requirements for monthly benefits, but not for more than 12 months before the month in which he files his application.

HI ends with the month the individual ceases to be entitled to monthly social security benefits and/or ceases to be a qualified railroad retirement beneficiary (for example, a woman whose wife's benefits are terminated by divorce). A person who ceases to be a social security or railroad retirement beneficiary but who meets the requirements of the special transitional provision or the special provision for premium payment hospital insurance may reinstate HI by filing a proper application under either of those provisions.

105.2 Transitional Provision for the Uninsured.--Special provision was made to extend coverage to many older people who did not have social security insured status at the time Medicare began in 1966. Under this provision, people attaining age 65 by 1974 were permitted to qualify for HI with less work credits than are necessary to receive monthly social security benefits. Practically all persons eligible under this provision have already been awarded HI. Persons over 65 who do not have HI should get in touch with their local social security office for a determination of eligibility.

105.3 Hospital Insurance for Persons Needing Kidney Transplant or Dialysis.--Effective July 1, 1973, individuals under age 65 who need dialysis or renal transplantation for chronic renal disease are eligible for HI (and are deemed enrolled for Part B unless such coverage is refused) if they (a) meet certain work requirements for insured status under the social security program, or (b) are entitled to monthly social security benefits, or an annuity under the Railroad Retirement Act, or (c) are the spouses or dependent children of an individual falling into either category (a) or (b).

Eligibility for HI begins with the first day of the third month after the month in which a course of renal dialysis begins, unless the person receives a transplant in or before such third month. In the latter event, eligibility begins with the month of transplantation, or with the prior month if the person was hospitalized in that month in anticipation of and in preparation for such transplant surgery. Eligibility is based on the earliest entitlement date when someone could possibly qualify under several different provisions.

Hospital Insurance coverage based on having end stage renal disease ends with the earliest of the following dates: (a) the date an individual dies; (b) the last day of the twelfth month after the month in which (1) a person receives a kidney transplant or (2) the course of dialysis is discontinued. For example, if a person received a kidney transplant on October 10, 1975, Hospital Insurance entitlement would terminate on October 31, 1976. If the transplant failed and a regular course of dialysis was initiated within the 12-month period, entitlement would continue.

It is important that persons under 65 years of age report to their social security office when they are transplanted or have begun a regular course of dialysis.

105.4 Hospital Insurance for Disability Beneficiaries.--Effective July 1, 1973, beneficiaries under age 65 who have been entitled to disability benefits under the Social Security Act for at least 24 consecutive months are entitled to HI beginning with the 25th month of the entitlement and are deemed to have enrolled in SMI unless this coverage is refused. Railroad Retirement Act annuitants who meet the same disability criteria as disabled social security beneficiaries can also become entitled under this provision. (Since railroad disability annuitants do not serve a disability waiting period, their health insurance entitlement will begin after they have received disability benefits for a period comparable to the social security waiting period plus 24 months.) Those who can obtain coverage include disabled workers under age 65, disabled widows, and disabled dependent widowers between the ages of 50 and 65, women age 50 or older entitled to mother's benefits who, for 24 months prior to the first month they would have been entitled to Medicare protection, met all the requirements for disability benefits except for actual filing of a disability claim, people age 18 and over who receive social security benefits because they became disabled before reaching age 22, and disabled qualified railroad annuitants. Disabled mothers must be at least age 52, and disabled children at least age 20, before entitlement to Medicare can begin because of the requirement that they be entitled to the disability based benefit for 24 consecutive months.

HI and SMI coverage for beneficiaries under age 65 who qualify under this provision terminates the month the disability benefit terminates or the month following the month that a notice of disability termination is mailed to the beneficiary, whichever is later.

106. SUPPLEMENTARY MEDICAL INSURANCE ENTITLEMENT

106.1 Eligibility for Enrollment.--To obtain SMI, an eligible individual must enroll during an enrollment period and pay the required premiums. He is eligible to enroll if he either (1) is entitled to HI (see §105.1 - 105.4), or (2) is 65 years old and is a resident citizen or an alien who meets certain residence requirements.

Payment may be made for covered services if the individual had coverage at the time the services were furnished, even though his enrollment had terminated at the time the request for payment was filed with the intermediary.

106.2 Automatic Enrollment after June 1973.--Eligible individuals (except those residing in foreign countries or Puerto Rico) who first become entitled to HI on or after July 1, 1973, are deemed enrolled for SMI as follows:

An individual under 65 who becomes entitled to HI has SMI beginning with the first month of HI entitlement.

A beneficiary who is already on the monthly benefit rolls when he attains age 65 has HI and SMI effective with the month he attains age 65.

For an insured person filing for monthly benefits within 3 months before or after the month he attains age 65 (i.e., within his initial enrollment period (IEP)) SMI coverage begins at 65 or within 6 months thereafter, depending upon when he filed the application establishing his HI entitlement. If the application establishing his entitlement to HI is filed more than 3 months after age 65 and outside any GEP (defined below), he will be deemed to have enrolled in the next GEP and his coverage will begin on July 1 after the GEP. Every person subject to automatic enrollment is given a reasonable opportunity to decline SMI by filing timely notice with SSA.

106.3 Enrollment Periods.--Enrollment for those not subject to automatic enrollment or who refuse automatic enrollment is possible only during certain enrollment periods:

1. An individual's initial enrollment period (IEP) lasts for 7 months. It begins 3 months before and ends 3 months after the month he attains age 65 (or, if later, the month he first meets all the requirements for enrollment).

2. A general enrollment period (GEP) occurs each year from January 1 through March 31. A person enrolling in a GEP has coverage effective the following July 1.

The GEP's provide opportunities to those who failed to enroll during the initial enrollment period, to those who refused automatic enrollment in SMI, and to those whose enrollment has terminated. However, a person cannot enroll for SMI more than twice.

106.4 State "Buy-In."--A State which has entered into a buy-in agreement with SSA may enroll indigent persons eligible for SMI. The State may enroll such persons at any time after they qualify for buy-in regardless of enrollment periods and number of prior enrollments (see § 106.6). The State pays the SMI premiums for the persons it enrolls.

106.5 When Coverage Ends.--SMI coverage ends when any of the following events occur:

a. the person dies;

b. HI coverage ends for the enrollee who is under age 65 (see § 105.3 and 105.4);

c. the person voluntarily withdraws;

d. the person no longer qualifies for the State buy-in (e.g., his income increased above the limit) AND he does not exercise his option to pay the premiums himself;

e. the SMI premiums have not been paid within the grace period as defined below in § 106.7C.

Dialysis treatment centers must promptly report to SSA if a kidney transplant is received or dialysis is discontinued. Such notices may be sent to either the Bureau of Disability Insurance, P.O. Box 18, Baltimore, Maryland 21203, or any social security office. They must include the following information: the beneficiar's name, address, and claim number; the event which occurred (kidney transplant or dialysis discontinued) and the date of the event; the name and address of the facility which provided the service or, if dialysis was discontinued, provided the last dialysis service.

106.6 Termination and Reenrollment.--An individual whose enrollment has terminated may reenroll only once and this must occur in a general enrollment period. However, whenever an individual is covered under a State buy-in agreement which ends, his coverage continues as though he had individually enrolled in his initial enrollment period. If that coverage ends, he has an opportunity to reenroll in a general

enrollment period. This is regardless of the number of his prior individual enrollments. He may reenroll once each time he has a new period of State buy-in coverage followed by an individual enrollment which terminates. (Prior to the 1972 amendments, individuals were required to enroll for SMI within 3 years following initial eligibility. Any individual previously ineligible to enroll because of the 3-year limit may enroll during any general enrollment period.)

106.7 Premiums

A. Amount of Premium.--The law requires the Secretary of Health, Education, and Welfare to adjust the premium amount to meet the costs of the program. The Secretary determines and announces during December of each year the premium rate applicable for the 12-month period beginning with the following July 1. The Secretary's premium rate change announcement always includes the actuarial assumptions and other bases used to determine the new rate.

Effective with the premium for the year beginning July 1973, premium increases cannot take place unless there has been a general social security benefit increase since the current premium amount was established. Additionally, the percentage of increase cannot exceed the percentage of the general social security benefit increase. The premium will be determined on the basis of program costs for aged enrollees, rather than the higher costs for the disabled enrollees. General revenues are used to pay any unmet program costs resulting from this provision.

Premiums payable by a person who enrolls later than the first enrollment period open to him or who reenrolls after his initial enrollment was terminated are increased by 10 percent for each full 12 months he could have been, but was not, enrolled. Months in which the law formerly precluded enrollment because of the 3-year limit will not be counted in determining the premium increase. The Federal government contributes at least half the costs of SMI for the aged.

There is no premium increase during the deemed individual enrollment that follows termination of State buy-in coverage. If that deemed individual coverage ends, the amount of premium increase is measured beginning with the month following the month in which the coverage ended.

B. Payment of Premium.--Social security beneficiaries, railroad retirement beneficiaries, and civil service annuitants (except those enrolled by the State as public assistance recipients) who elect Part B coverage will have the premium withheld from their monthly checks. The State pays the premium for the public assistance recipients and medical assistance eligibles it enrolls including, in most States, those who are social security and railroad retirement beneficiaries or civil service annuitants. Other enrollees must make premium payments in response to quarterly billing. State or local government organizations, employers, unions or other organizations may desire to pay premiums for their members who would otherwise pay their premiums by direct remittance. If the organization's enrollee group includes at least 100 members who have authorized the group to pay their premiums, a single bill for the group will be rendered monthly. Any organization interested in paying Part B premiums should get in touch with the nearest Bureau of Health Insurance Regional Office. Local social security offices also may be contacted for information.

C. Grace Period for Premium Payment.--A grace period extends for 90 days after the month in which the premium is due to prevent a hasty termination of SMI for failure to pay premiums. This 90-day grace period for paying overdue SMI premiums and continuing SMI coverage may be extended by SSA for good cause for up to an additional 90 days, the total not to exceed 180 days. Good cause, for example, would be found if the enrollee was mentally or physically incapable of paying his premiums timely, or his failure to pay timely was due to administrative error.

Cash Deductibles and Coinsurance

108. PART A INPATIENT HOSPITAL DEDUCTIBLE

The patient is responsible for a deductible amount for inpatient hospital services in each benefit period. The year in which the patient's benefit period begins determines the deductible amount during such period.

The deductible amount is subject to change by the Secretary who is required to determine annually the amount of the deductible. The following chart reflects the amount of inpatient hospital deductible:

Year in Which Benefit Period Begins

In 1973	In 1974	In 1975	In 1976	In 1977
$72	$84	$92	$104	$124

The year in which the benefit period begins determines not only the deductible amount to be applied during such benefit period, but also the coinsurance amounts for inpatient hospital services furnished in the same benefit period.

The deductible is satisfied only by charges for covered Part A services. Expenses for covered services count toward the deductible on an incurred rather than paid basis. Expenses incurred in one benefit period cannot be applied toward the deductible in a later benefit period. Expenses incurred in meeting the blood deductible do not count toward the inpatient hospital deductible.

110. PART A INPATIENT HOSPITAL COINSURANCE

The patient is responsible for a coinsurance amount equal to one-fourth of the inpatient hospital deductible for each day after the 60th day and through the 90th day of inpatient hospital services furnished during a spell of illness. Where the actual charge to the patient is less than the benefit period coinsurance rate for the benefit period, the coinsurance is the actual charge per day. In billing both the patient and the program, the coinsurance amount is the same.

For services furnished after December 31, 1967, inpatient hospital beneficiaries have an available 60-day lifetime reserve for inpatient hospital services. Unless a beneficiary elects not to use this reserve, he will be responsible for a coinsurance amount for each day used equal to one-half of the inpatient hospital deductible for the spell of illness in which such reserve days are used.

Both coinsurance amounts are determined by the year in which the patient's benefit period begins.

The following chart should be used to determine the applicable coinsurance amount for a day of inpatient hospital service from the 61st through 90th day:

Year in Which Benefit Period Begins

In 1973	In 1974	In 1975	In 1976	In 1977
$18	$21	$23	$26	$31

The following chart should be used to determine the applicable coinsurance amount for a lifetime reserve day:

Year in Which Benefit Period Begins

In 1973	In 1974	In 1975	In 1976	In 1977
$36	$42	$46	$52	$62

EXAMPLE 1: An HI beneficiary enters a qualified hospital in Jaunary 1975 beginning a benefit period with this admission. For as long as this benefit period continues, the amount of the inpatient deductible will be $92, the coinsurance amount for each day from the 61st through the 90th will be $23, for a lifetime reserve day $46.

EXAMPLE 2: A beneficiary begins a benefit period with admission to a hospital in December 1974 and pays an $84 inpatient hospital deductible. He continues to be hospitalized in the same benefit period after December 31, 1974. The coinsurance amount for each day of inpatient hospital services from the 61st through 90th day will be $21, for a lifetime reserve day $42.

112. PART B SUPPLEMENTARY MEDICAL INSURANCE DEDUCTIBLE
In each calendar year a cash deductible must be satisfied before payment can be made under the supplementary medical insurance plan. The cash deductible for expenses incurred from 1/1/73 on is $60. Expenses incurred in the last three months of a calendar year which were applied toward the deductible for that year are also applied toward the deductible in the following year.

Bills count toward the deductible on the basis of incurred, rather than paid expenses, and are based on the reasonable charge. Non-covered expenses do not count toward the deductible. Even though an individual is not eligible for the entire calendar year, i.e., his insurance coverage begins after the first month or he dies before the last month of the year, he is still subject to the full cash deductible. Medical expenses incurred in the portion of the year preceding entitlement to medical insurance are not credited toward the deductible.

The date of service determines when expenses were incurred, but expenses are allocated to the deductible in the order in which the bills are received by the intermediary. An adjustment must be made when expenses incurred in the fourth quarter of one year are used to satisfy the deductible for the following year and it is subsequently determined that the patient had incurred covered expenses prior to the fourth quarter of the earlier year.

114. PART B SUPPLEMENTARY MEDICAL INSURANCE COINSURANCE
After the annual deductible has been satisfied providers are paid 80 percent of their reasonable costs, and physicians, suppliers and most non-hospital renal dialysis facilities are paid 80 percent of their reasonable charges. Non-hospital renal dialysis facilities submit their bills to their Medicare intermediary and the patient is responsible only for any portion of the annual deductible not met and for the 20 percent coinsurance.

When a Medicare beneficiary receives covered Part B services from a physician or supplier (someone other than a facility), the Medicare payment can be made directly to the physician or supplier, or it can be made directly to the beneficiary. The assignment method, in which the doctor or supplier receives the Medicare payment directly, can be used only if both the patient and doctor or supplier agree to it. If the doctor or supplier agrees to use the assignment method, he also agrees to accept the reasonable charge set by the Medicare carrier as his total charge for the service. The doctor or supplier cannot charge the patient for any more than 20 percent of the Medicare reasonable charge, any part of the $60 annual deductible not met, and for any non-covered services. If the assignment method is not used, the physician or supplier bills the patient directly. The patient, in turn, submits either the bill or a receipt to his Medicare carrier. The carrier makes direct payment to the beneficiary of 80 percent of the reasonable charges, after subtracting any part of the annual deductible that has not been met.

Instructions to Medicare beneficiaries on how to submit Part B claims are furnished them by SSA in a document entitled, "Your Medicare Handbook." Extra copies are available from any social security office.

Blood Deductibles (Part A and Part B)

116. BLOOD DEDUCTIBLES
(This section is included for informational purposes only. When blood is furnished in a non-hospital renal dialysis setting, it must be billed to the Part B carrier in the name of the physician who supervised its administration. See specific instruction on this in the Bill Processing chapter.)

116.1 Part A Blood Deductible.--Program payment may not be made for the first three pints of whole blood or equivalent units of packed red cells received by a beneficiary in a benefit period. However, payment may be made for blood processing beginning with the first pint or unit in a benefit period.

The Part A blood deductible applies only to the first three pints of blood furnished in a benefit period, even if more than one provider furnished blood. The Part A and Part B blood deductibles are applied separately. The blood deductibles are in addition to any other applicable deductible and coinsurance amounts for which the patient is responsible.

To be covered as a Part A service and count toward the blood deductible, the blood must be furnished on a day which counts as a day of inpatient hospital services. Thus, blood is not covered under Part A and does not count toward the Part A blood deductible when furnished to an inpatient after he has exhausted his benefit days in a benefit period, or where the individual has elected not to use lifetime reserve days. However, where the patient is discharged on his first day of entitlement or on the provider's first day of participation, the provider is permitted to submit a billing form with no accommodation charge, but with ancillary charges including blood.

116.2 Part B Blood Deductible.--Where blood is furnished on an outpatient basis, it is subject to a Part B blood deductible applicable to the first three pints of whole blood or equivalent units of packed red cells received by a beneficiary in a calendar year. It should be noted that payment for blood under Part B is possible only for blood furnished in an outpatient setting.

The Part B blood deductible applies only to the first three pints of blood furnished in a calendar year, even if more than one provider furnished blood. The Part A and Part B blood deductibles are applied separately. The blood deductibles are in addition to any other applicable deductible and coinsurance amounts for which the patient is responsible. Any questions concerning payment or nonpayment of the blood deductible should be referred to your intermediary.

Administration of Medicare Program

118. FEDERAL GOVERNMENT ADMINISTRATION OF THE HEALTH INSURANCE PROGRAM
The Department of Health, Education, and Welfare has been given overall responsibility for administration of the hospital insurance and medical insurance programs.

The law specifically prohibits the Federal Government from exercising supervision or control over the practice of medicine, the manner in which medical services are provided, and the administration or operation of medical facilities. The patient is free to choose any qualified institution, agency, clinic, or person offering him services. The responsibility for his treatment and the control of his care remains with his physician and the organization furnishing him services. The individual may keep or obtain any other health insurance available, if he desires.

119. THE HEALTH INSURANCE BENEFITS ADVISORY COUNCIL
A Health Insurance Benefits Advisory Council consisting of persons outstanding in hospital, medical, and other health activities, persons who are representative of professional organizations and associations in the field of medicine, and at least one representative of the general public, advises the Secretary on general policy in administering the program and in the formulation of regulations. The Secretary must consult with the Council in determining conditions of participation for providers of services in addition to the requirements specifically enumerated in the law. The Council also studies the utilization of medical services under the program and makes any recommendations to the Secretary and to Congress that it considers appropriate.

120. STATE AGENCIES
The States are accorded important administrative functions to the extent that each is willing and able to undertake them by agreement with the Secretary.

A. Certifications are made by State agencies to the Department of Health, Education, and Welfare indicating whether providers of services, including renal dialysis facilities, clinics, rehabilitation agencies, and public health agencies providing outpatient physical therapy services, meet and continue to meet their respective conditions of participation. This function is intended to be a natural adjunct to ongoing State activities, such as licensing of health facilities and other standard setting activities. The ESRD program follows the pattern of other Medicare-approved facilities in that survey visits will be made (either directly by personnel of the Department of HEW on behalf of the Secretary or by the contractual agency in each State's health department functioning as the Medicare State survey agency) to each facility desiring ESRD program approval.

B. Consultation services are rendered by State agencies if their agreements provide for it. Consultation with hospitals, skilled nursing facilities, home health agencies, clinics, rehabilitation agencies, and public health agencies that need and request assistance to meet the conditions of participation is an integral part of the certification process.

C. The State coordinates its activities under the Medicare program with the various other programs in the State that have to do with payment for health care, quality of care, and distribution of health facilities. Coordination of such activities is designed to utilize existing State facilities and trained personnel effectively and economically and to prevent duplication of effort.

D. Where a State enters into an agreement with the Federal Government as a medical insurance carrier to pay the medical insurance premium on behalf of its aged welfare recipients, the agreement may provide for a designated State agency to serve as an intermediary on behalf of its welfare recipients.

122. INTERMEDIARIES AND CARRIERS

The Part A intermediary is a public or private agency or organization that has entered into an agreement with the Health Care Financing Administration to process Medicare claims under both Part A and Part B of providers of services, i.e., hospitals, skilled nursing facilities, home health agencies, outpatient physiczl therapy and speech pathology providers, and renal dialysis facilities. (Providers and nonhospital renal dialysis facilities may elect to deal directly with the Health Care Financing Administration.)

Intermediaries make payments to providers; the amount of reimbursement to any provider is restricted to the lesser of (a) the reasonable cost of covered services and items or (b) the customary charges with respect to such services. In addition, intermediaries assist in the application of safeguards against the unnecessary use of covered services, furnish consultive services to assist in the establishment and maintenance of requisite fiscal data, serve as a center for communicating with providers, conduct audits of provider records, assist in the beneficiary appeals process, and provide information and advice to institutions and organizations that wish to qualify as providers of services.

The law requires the Secretary to enter into contracts with carriers to serve as intermediaries in the operation and administration of the nonprovider Part B program. A principal function of these carriers is to determine whether charges of physicians (including facility-based physicians) and suppliers for covered Part B services constitute "reasonable charges" within the meaning of the law, and to make payment. Other major functions include, for example, controlling overutilization and communicating with the health community.

All billings for renal dialysis facility services are to be submitted on Form SSA-1483, "Provider Billing for Medical and Other Health Services" plus special supplemental forms. Facility billings will be processed by Part A intermediaries. Renal dialysis facilities should bill for dialysis services on a monthly basis.

Disclosure of Information

124. DISCLOSURE OF HEALTH INSURANCE INFORMATION--GENERAL
All records and information acquired in the administration of the Social Security Act are confidential and may be disclosed only under the conditions prescribed in rules and regulations or on the express authorization of the Commissioner of Social Security. Regulation No. 1 of the Social Security Administration regarding the confidentiality of records and information applies to governmental and private agencies participating in the administration of the program; to institutions, facilities, agencies, and persons providing services; and to those furnishing services under arrangement with a provider of services.

Information furnished specifically for purposes of a claim under the health insurance program is subject to these rules and regulations. Such information includes the individual's health insurance claim number, proof of his entitlement to health insurance benefits, and medical and other information obtained from the Health Care Financing Administration (HCFA) or an intermediary.

However, the information in a facility's own records of a patient (e.g., name, date of birth, sex, marital status, address, medical records) is not subject to these rules and regulations, even though the patient receives benefits under the health insurance program. The facility's own records, however, are subject to the requirements in the "Conditions of Participation; Hospitals" that patients" medical records be kept confidential (20 C.F.R. Part 405.1026). These records may also be subject to State or local laws governing disclosure.

When a facility receives a request for information about a Medicare beneficiary, a Medicare claim, or related information which it may not disclose, the inquirer should be referred to the appropriate intermediary for further consideration of his request.

125. DISCLOSURE OF HEALTH INSURANCE INFORMATION TO A BENEFICIARY, OR IN CONNECTION WITH A CLAIM

125.1 Disclosure to the Beneficiary or His Authorized Representative.--

A. General.--Information directly relating to the beneficiary, such as Medicare entitlement or eligibility data, may be disclosed to the individual or his authorized representative (including his legal representative).

B. Medical Information.--Facilities may not forward medical information to intermediaries on a confidential basis, expressed or implied, since under the Privacy Act any medical information obtained by an intermediary is subject to disclosure to the individual to whom it pertains, or to another person authorized by the individual to have access to it.

Some facilities document findings on medical forms preprinted "confidential," or routinely stamp all records "confidential," whether or not such records are ever intended for disclosure to an intermediary. Such records, when transmitted to the intermediary, will be accepted only if accompanied by a signed statement that the facility understands the information is subject to disclosure to the patient under the Privacy Act and any words or statements that the transmitted records are confidential may be disregarded if the patient or his representative requests them from the intermediary or from SSA. The repeated preparation and forwarding of separate signed statements can be obviated if the facility signs an appropriate general statement of understanding with the intermediary that medical information may be disclosed to the individual under the Privacy Act, even if it is routinely designated "confidential."

125.2 Disclosure to Third Parties for Proper Administration of the Health Insurance Program.--Disclosure by the facility to persons other than the individual or his authorized representative of any records, reports, or other information about the individual is authorized without his consent in connection with any claim or other proceeding under the Social Security Act only when disclosure is necessary for the proper performance of the duties of:

A. Any officer or employee of the Department; or

B. Any officer or employee of a State agency, intermediary, provider of services, or other agency or organization participating in the administration of the program by contract or agreement in carrying out such contract or agreement.

These limitations apply whether or not the individual to whom the information pertains authorizes further disclosure to third parties (e.g., to a private medical plan).

126. DISCLOSURE OF INFORMATION ABOUT FACILITIES BY HCFA

The following information about facilities participating in the Medicare program may be disclosed by HCFA under the Freedom of Information Act in response to requests from the public.

126.1 Medicare Reports.--

A. Provider Survey Report and Related Information.--Information concerning survey reports of facilities as well as statements of deficiencies, based on survey reports completed after January 31, 1973, are available at the local social security office or the public assistance office in the area where the facility is located. The following data may be released under this provision:

1. The official Medicare report of a survey concluded on or after January 31, 1973;

2. Statements of deficiencies which have been conveyed to the facility following a survey concluded on or after January 31, 1973;

3. Plans of correction and pertinent comments submitted by the facility relating to Medicare deficiencies cited following a survey concluded on or after January 31, 1973.

State agencies certify whether institutions or other entities meet the Medicare conditions of participation. A State agency may disclose information it obtains relating to the qualifications and certification status of facilities it surveys.

B. Program Validation Review Reports and Other Formal Evaluations.--Upon written request, official reports and other formal evaluations of the performance of facilities completed after January 31, 1973, are made available to the public. After the survey reports and other formal evaluations are prepared by personnel of the Social Security Administration, the evaluated facility must be given an opportunity (not to exceed 30 days) to review the report and submit comments on the accuracy of the findings and conclusions. The facility's comments must be incorporated in the report if pertinent.

Program validation review reports are generally released from the Bureau of Health Insurance regional office serving the area in which the facility is located.

Generally, informal reports and other evaluations of the performance of facilities which are prepared by the intermediary are available to the public.

C. Facility Cost Reports.--

1. General.--Requests by any member of the public either to inspect or to obtain a copy of a facility cost report must be submitted to BHI or the intermediary in writing and must identify the facility and specific cost report(s) in question.

Intermediaries are required to respond to requests in writing within 10 working days after receipt of a written request, to advise the requestor of the date the reports will be made available. That date will be no earlier than 10 working days from the date of the intermediary's response. A copy of the response to the requestor will be sent simultaneously to the facility putting the facility on notice that its report has been requested by a particular person. If a request is for a report submitted by a former owner of a facility, copies of the intermediary's response to the requestor will go to both the present owner and the former owner of the facility. If the request is for a report submitted by a facility no longer participating in the Medicare program, a copy of the intermediary's response will be sent to the facility. In the case of both a former owner and a former participating facility, the copy of the response will be sent to the last known address of the party.

2. Information That May be Disclosed.--Disclosure by the intermediary is limited to cost report documents which facilities are required by BHI regulations and instructions to submit and, in case of a settled cost report, the intermediary's notice of program reimbursement. These documents include the statistical page, the settlement pages, trial balance of expenses, and cost finding schedules or documents required by BHI as part of the regular cost report process. (Where a facility, after first obtaining program approval, has submitted equivalent documents in lieu of official program documents, these documents are subject to the same disclosure rules as official forms.)

If a request is received to inspect or to obtain a copy of a report that has not been settled, i.e., the final settlement notice of program reimbursement has not been sent, the intermediary will disclose a copy of the report as submitted by the facility. If settlement has been made, the intermediary will disclose the settled report. If a requestor specifically asks for both the settled and unsettled cost reports of a facility, the intermediary will comply with such request. When a report is made available for inspection or copying, it will be clearly marked with one of the following captions, as applicable:

a. Cost report as submitted

b. Settlement subject to audit

c. Audited settlement

When an intermediary discloses a settled report, schedules applicable to the settlement that have been reworked by the intermediary are disclosable. The general rule is that if the intermediary has reworked any of the schedules that were required to be submitted by the facility with its original submission, these schedules become an integral part of the report for disclosure purposes. However, any details containing intermediary or auditor comments concerning the settlement, details of specific adjustments, or supporting schedules applicable to the settlement of the facility's operation are not disclosed by the intermediary.

Information obtained in auditing facility cost reports and other financial records may be released by HCFA.

3. Information That May Not be Disclosed.--If a facility chooses to submit with its cost report additional information not specifically required by regulations or instructions, the intermediary will not disclose such information unless it is contained within an official document. For example, some facilities may submit supplementary analyses of certain expenses, details of the professional component adjustment, financial statements (other than the statement of income and expenses and the balance sheet as required in accordance with cost reporting instructions), or income tax returns, etc., that are not required by the program. These items would not be disclosed by the intermediary as part of the cost report.

Except where a facility has not submitted an acceptable cost report and supplements are required to complete the report, any additional documents or schedules that the intermediary requires the facility to submit in support of its cost representations would also not be disclosed by the intermediary as part of the cost report. In addition, the following are not disclosed by the intermediary as part of a cost report: audits, schedules, letters, notes, general comments; comments on results of desk reviews (including copies of the actual desk review documents), intermediary notices and comments (including transmittal letters), audit adjustment summaries that are required to be prepared by intermediaries and auditors, and information pertianing to an individual patient.

NOTE: Any of the information indicated above that is not to be disclosed by the intermediary may be subject to disclosure under the Freedom of Information Act upon review by the Health Insurance Regional Office, Central Office, or a U.S. District Court in response to a request for such information. The description of what will be made available by an intermediary as part of a cost report pertains only to requests that indicate that the requestor specifically wants cost reports.

126.2 Disclosure of Medicare Statistics.--Numerous statistics on individual facilities are available to the public. They include, but are not limited to, the following:

1. Waiver of liability statistics

2. Interim rate payment data

3. Amount of Medicare reimbursement

4. Overpayment data

5. Data from the Provider Monitor Listing

6. Information from the Directory of Medical Facilities and the Directory of Medicare Providers and Suppliers of Services

7. Medicare inpatient statistics (e.g., total inpatient days, number of admissions, average length of stay).

126.3 Other Information That May be Disclosed.--

1. Presumptive waiver of liability status of the facility:

2. Information as to whether a facility participates in the Medicare program.

Fraud

128. FRAUD AND PENALTIES

All documents providers submit to intermediaries for the purpose of receiving title XVIII Medicare payments are considered claims upon or against the United States, and payments made on such claims represent Federal funds.

Therefore, deliberate submission of a claim containing statements and representations known to be materially false, for the purpose of obtaining unauthorized payments, may constitute violation of the penal provisions of the Social Security Act and/or the Federal Criminal Code. These statutes variously provide for a fine of not more than $10,000 or imprisonment for not more than five years, or both, for each claim proven criminally false. Furthermore, reuglations of the Federal government General Accounting Office require that payments be suspended where the evidence of improper activity is sufficient to warrant referral to the Department of Justice, for consideration of prosecution.

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COVERAGE OF SERVICES
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200. HEALTH INSURANCE COVERAGE OF PERSONS NEEDING KIDNEY TRANSPLANTATION OR DIALYSIS -- GENERAL

This chapter discusses the Medicare coverage of the primary treatments used to preserve the life of patients with end-stage renal disease: live donor or cadaveric donor transplants, or a continuous dialysis program. Although transplantation can occur only in approved hospitals, general coverage information is included in this manual for possible use in responding to general inquiries. Technical inquiries concerning Medicare coverage of transplants should be referred to the local social security office.

Dialysis treatments are covered in various settings: hospital inpatient, hospital outpatient, non-hospital renal dialysis facility, or patient's home. There are varying levels of care in the different settings. Initially, the seriously ill patient may be treated as an inpatient at a hospital. After stabilization, treatments are rendered in an outpatient setting at either the hospital or a non-hospital facility. In any of the renal dialysis facilities he may receive extensive attention and professionals may perform all services needed in dialysis or the patient can be placed in "self-care" where only minor assistance is given by facility technical personnel. In any of the settings a patient can be taught to dialyze at home. In connection with covered home dialysis, medically necessary items of durable medical equipment and the supplies used on or in that equipment are generally reimbursable under the Medicare program.

202. SPECIFIC MEDICARE APPROVALS REQUIRED BY RENAL DIALYSIS FACILITIES

All facilities providing maintenance renal dialysis treatments to Medicare patients must meet conditions for coverage before they can qualify for Medicare reimbursement. Initially, interim regulations provided reimbursement to those facilities that were furnishing such care prior to July 1973. These regulations also described criteria for evaluating and approving facilities that began operations or expanded after that date. On June 3, 1976, final "long term" regulations were published in the Federal Register (Vol. 41, No. 108, pp. 22502-22522, Regulations No. 5, Subpart U, § 405.2100 ff.). These regulations provide for State health departments, in conjunction with Department of Health, Education, and Welfare regional offices, to survey and certify facilities furnishing end-stage renal disease (ESRD) treatment services for compliance with health, safety, and other Medicare requirements.

Questions relating to the above cited regulations, the survey process, or a facility's status as an approved supplier of ESRD services should be referred to the nearest Medicare Bureau Regional Medicare Director.

204. DISCRIMINATION PROHIBITED

All Medicare facilities participating under the program must comply with the requirements of Title VI of the Civil Rights Act of 1964. Under the provisions of that Act, they are prohibited from making a distinction on the ground of race, color, or national origin in the admission and treatment of patients; the accommodations provided; the use of equipment and other facilities; and the assignment of personnel to provide services.

The Department of Health, Education, and Welfare is responsible for investigating complaints of noncompliance.

206. COVERAGE OF DIALYSIS SERVICES -- GENERAL

Dialysis treatments at renal dialysis facilities are subject to some variation, depending on such things as the types of patients being treated, the type of equipment and supplies used, the preferences of the treating physician, and the capability and makeup of support staff. Although all facilities do not provide identical ranges of services, the most common elements of a dialysis are: personnel services (physician, registered nurse, licensed practical nurse, technician, social worker, dietitian); equipment and supplies (dialysis machine and its maintenance, disposable supplies); some laboratory tests; overhead and general administrative services.

Renal dialysis facilities develop a unit charge for the range of services normally provided, taking into account variations among patients (complicated and non-complicated situations) since it is the overall dialysis service that is covered. Any auxiliary service which cannot be included in the single unit charge for dialysis services as an integral part of a maintenance dialysis must be includable under another specific coverage provision of the Medicare law, or be denied. For example, the Medicare law excludes from coverage out of hospital drugs except when specified conditions are

met with respect to the physician's involvement. Furthermore, when the conditions are met, the drug and injection charges must be billed to the carrier by the physician.

Any questions about coverage based on a unique pattern of providing dialysis services should be referred to the intermediary. However, the following sections dealing with specific coverage issues should be sufficient to answer most inquiries.

207. SPECIFIC COVERAGE ISSUES RELATING TO DIALYSIS TREATMENTS

207.1 Laboratory Services Included Under the Composite Rate.--The costs of certain ESRD laboratory services performed by either the facility's staff or an independent laboratory are included in the composite rate calculations. Therefore, payment for all of these tests is included in the facility's composite rate and may not be billed separately to the Medicare program. These tests are either performed by the facility, in which case reimbursement is included in the composite rate, or by an outside laboratory for the facility, in which case the laboratory bills the facility and is reimbursed only under the composite rate. These laboratory tests are listed in §207.3 and §240.3D.

207.3 Laboratory Tests for Hemodialysis, Intermittent Peritoneal Dialysis (IPD) and Continuous Cycling Peritoneal Dialysis (CCPD).--The tests listed below are usually performed for dialysis patients and are routinely covered, i.e., no additional documentation of medical necessity is required, at the frequency specified in the absence of indications to the contrary. When any of these tests are performed at a frequency greater than that specified, the additional tests are separately billable and will be covered only if they are medically justified by accompanying documentation. A diagnosis of ESRD alone is not sufficient medical evidence to warrant coverage of the additional tests. The nature of the illness or injury (diagnosis, complaint or symptom) requiring the performance of the test(s) must be present on the claim. A diagnosis from the ICD-9-CM coding system may be shown in lieu of a narrative description.

Per Treatment

All hematocrit and clotting time tests furnished incident to dialysis treatments.

Weekly

Prothrombin time for patients on anticoagulant therapy
Serum Creatinine
BUN

Monthly

Serum Calcium	Serum Bicarbonate	Alkaline Phosphatase
Serum Potassium	Serum Phosphorous	SGOT
Serum Chloride	Total Protein	LDH
CBC	Serum Albumin	

Automated Battery of Tests.--If an automated battery of tests, such as the SMA-12, is performed and contains most of the tests listed in one of the weekly or monthly categories above, it is not necessary to separately identify any tests in the battery that are not listed above.

The following list identifies certain separately billable laboratory tests that are covered routinely, i.e., without additional documentation of medical necessity, when furnished at the specified frequencies. If these tests are performed at a frequency greater than that specified, they will be covered only if they are medically justified by accompanying documentation. A diagnosis of ESRD will not be sufficient to justify additional payment. The nature of the illness or injury (diagnosis, complaint or symptom) requiring the performance of the test(s) must be present on the claim. A diagnosis from the ICD-9-CM coding system may be shown in lieu of a narrative description.

Guidelines for Separately Billable Tests for Hemodialysis, IPD, and CCPD,

Shown below is the recommended schedule for the administration of the hepatitis B vaccine. However, the actual frequency will be determined by the physician based on medical necessity.

Hepatitis B vaccine - 3 (two ml doses) doses

First dose
Second dose - 1 month after the first dose
Third dose - 6 months after the first dose

All vaccinees should be tested for antibody (hepatitis B surface antibody) to hepatitis B surface antigen no sooner than 1 month after the third dose of vaccine is administered to determine whether they have responded to the vaccine. Thereafter, individuals who have responded to the vaccine by showing evidence of surface antibody need only be tested annually for hepatits B surface antibody to confirm continued immunity.

For Seronegative Patients--(including patients who have received Hepatitis B vaccine but did not have a positive response to the vaccine) - Hepatitis B Surface Antigen Tests (HB_sAg) - one a month

Bone Survey (either the roentgenographic method or the photon absorptiometric procedure for bone mineral analysis) - one a year

Chest X-ray - one every 6 months

EKG - one every 3 months

Hepatitis B Surface Antibody or Hepatitis Core Antibody - one, but not both, once a year

Nerve Conductor Velocity Test (Peritoneal NCV) - one every 3 months

Serum aluminum - one every 3 months

Serum ferritin - one every 3 months

(See §240.3D for laboratory tests rendered to CAPD patients.)

EKGs and X-rays.--EKGs and X-rays are routinely covered. When furnished by an independent facility, these tests should be billed on the HCFA-1450. However, if the physician incurs a cost for these tests, he must bill the Medicare carrier on form HCFA-1500.

Hepatitis B Vaccine.--Vaccinations or inoculations are excluded from coverage as "immunizations" unless they are directly related to the treatment of an injury or direct exposure to a disease or condition. An exception was made in 1980 to include coverage of pneumococcal pneumonia vaccinations.

With the enactment of P.L. 98-369, coverage under Part B is extended to hepatitis B vaccine and its administration, furnished to a Medicare beneficiary who is at high or intermediate risk of contracting hepatitis B. This coverage is effective for services furnished on or after September 1, 1984.

High-risk groups currently identified include:

End-Stage Renal Disease (ESRD) patients;
Hemophiliacs who receive Factor VIII or IX concentrates;
Clients of institutions for the mentally retarded;
Persons who live in the same household as an Hepatitis B Virus (HBV) carrier;
Homosexual men;
Illicit injectable drug abusers.

Intermediate risk groups currently identified include:

Staff in institutions for the mentally retarded;
Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

Exception:

Persons in the above-listed groups would not be considered at high or intermediate risk of contracting hepatitis B, however, if there is laboratory evidence positive for antibodies to hepatitis B. (ESRD patients are routinely tested for hepatitis B antibodies as part of their continuing monitoring and therapy.)

For Medicare program purposes, the vaccine may be administered upon the order of a doctor of medicine or osteopathy--by home health agencies, skilled nursing facilities, ESRD facilities, hospital outpatient departments, persons recognized under the "incident to physicians' services" provision of law, and, of course, doctors of medicine and osteopathy.

A charge separate from the ESRD composite rate will be recognized and paid for administration of the vaccine to ESRD patients.

For physician reimbursement, refer to § 2745 of the Provider Reimbursement Manual, Part I.

Cross Refer §§ 240.3C and 240.3D

207.4 Patient Transportation Costs--Transportation to or from the dialysis facility is not a covered service.

Coverage of Medical Equipment and Supplies for Home Dialysis Patients

208. GENERAL

Home dialysis equipment and other medically necessary items of durable medical equipment prescribed by a physician are covered under Part B. The patient has the choice of buying or renting (leasing) the equipment. With the exception of purchased items costing $50 or less, which may be reimbursed in a single payment, Medicare pays for both rented and purchased equipment in monthly installments. Medicare makes monthly payments at a rate which approximates the reasonable monthly rental charge for similar equipment until its share of the reasonable purchase price is paid, or until the equipment is no longer medically necessary, whichever comes first. Likewise, when covered durable medical equipment is rented or leased, Medicare will pay its 80 percent of the reasonable rental (lease) charge as long as the equipment is medically necessary. Installment payments are made regardless of whether the patient pays for purchased equipment in a lump sum or in installments.

When payments stop because the beneficiary's condition has changed and the equipment is no longer necessary, the beneficiary is responsible for the remaining charges. Similarly, when payments stop because the beneficiary dies, his estate is responsible for the remaining charges. A beneficiary may sell or otherwise dispose of purchased equipment for which he has no further use. If after such disposal there is again medical need for similar equipment, Medicare payment can be made for the rental or purchase of that equipment.

Payment under Part B also may be made for the installation and delivery of durable medical equipment, for its repair, maintenance or replacement, as well as for expendable supply items essential to the effective use of the equipment. These items are covered only under the specified conditions discussed in the following sections. When covered these items are reimbursed in a lump sum, i.e., <u>not</u> in installments.

A variety of contractual agreements may be entered into by the patient for the leasing or purchase of home dialysis equipment and supplies. Manufacturers or suppliers may deal directly with a patient whom they look to for payment. Facilities may purchase equipment and supplies for resale or lease to patients.

Finally, equipment or supplies may be furnished to a patient by a manufacturer or supplier through a facility, i.e., items may be shipped directly to a patient but billed to a facility. All these arrangements are permitted under Medicare.

209. COVERAGE OF DURABLE MEDICAL EQUIPMENT

Reimbursement may be made under Part B for 80 percent of the reasonable charge for durable medical equipment which is rented or sold to a Medicare beneficiary for use in the home if the following three requirements are met:

a. The equipment meets the definition of durable medical equipment (§ 209.1); and

b. The equipment is necessary and reasonable for the treatment of the patient's condition. (§ 209.2); and

c. The equipment is used in the patient's home.

209.1 Definition of Durable Medical Equipment.--For purposes of coverage under Part B, durable medical equipment is equipment which (1) can withstand repeated use, (2) is primarily and customarily used to serve a medical purpose, (3) generally is not useful to a person in the absence of illness or injury and (4) is appropriate for use in the home. All requirements of the definition must be met before an item can be considered to be durable medical equipment.

A. Durability.--An item is considered durable if it can withstand repeated use; i.e., the type of item which could normally be rented. Medical supplies that are disposable are not considered "durable" within the meaning of the definition.

B. Medical Equipment.--Medical equipment is equipment which is primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury. In most instances, no development will be needed to determine whether a specific item of equipment is medically necessary. However, some cases will require development to determine whether the item constitutes medical equipment. This development would include the advice of local medical organizations (hospitals, medical schools, medical societies) and specialists in the field of physical medicine and rehabilitation. If the equipment is new on the market, it may be necessary, prior to seeking professional advice, to obtain information from the supplier or manufacturer explaining the desgin, purpose, effectiveness and method of using the equipment in the home as well as the results of any tests or clinical studies that have been conducted.

209.2 Necessary and Reasonable.--Although an item may be classified as durable medical equipment, it may not be covered in every instance. Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for treatment of the patient's condition. These considerations will bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial payment when the type of equipment furnished substantially exceeds that required for the treatment of the illness or injury involved.

A. Necessity for the Equipment.--Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's condition. In most cases the physician's prescription for the equipment will be sufficient to establish that the equipment serves this purpose. The prescription must state the duration of medical necessity. For most renal disease patients this will be "indefinite."

B. Reasonableness of the Equipment.--Even though an item of durable medical equipment may serve a useful medical purpose, the intermediary will also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed.

C. Payment Consistent with What is Necessary and Reasonable.--Medicare reimbursement is limited to the reasonable charge for equipment or alternative treatment which meets the patient's medical needs. Payments may be restricted where equipment furnished contains features of an aesthetic nature or medical features not required by the patient's condition. The facility may not charge the patient for features not medically required by his condition unless the patient or his representative has specifically requested the excessive or deluxe items or services with knowledge of the amount he is to be charged.

210. CURRENT USE OF EQUIPMENT

Monthly rental payments or monthly installment payments for purchased items may be made only if the item was actually used during the month for which payment is claimed. Exception is allowed only under the circumstances outlined below.

Patients who normally dialyze at home occasionally have changes in regimen which result in the temporary non-use of the equipment. In circumstances where there is a likelihood of re-use, monthly rental charges (or monthly diary payments for a purchased item) may be continued for a period of up to three months after the month the equipment is last used. This instruction applies only to items of durable medical equipment necessary for home dialysis. It recognizes that under the circumstances listed below high installation charges could be paid a number of times for the same equipment if it is removed for temporary periods of non-use.

A. Beneficiary requires in-facility treatment either for restabilization or as a result of some acute condition. There is expectation that he will return to home dialysis.

B. Beneficiary temporarily is without a suitable home dialysis assistant.

C. Beneficiary is temporarily away from home but expects to return.

D. Beneficiary is a transplant candidate and is taken off home dialysis preparatory to transplant. (If the transplant cannot occur, or if the transplant is not successful, the patient will very likely resume home dialysis and an evaluation can be made whether it will be within the immediate or foreseeable future.)

Under such circumstances intermediaries and carriers may determine that medical necessity exists and pay for a period of up to three months after the month the home dialysis equipment was last used.

211. INSTALLATION AND DELIVERY

Medicare will cover all reasonable and necessary expenses incurred in the original installation of home dialysis equipment. This coverage is not extended to expenses attributable to home improvement, e.g., plumbing or electrical work beyond that necessary to tie in with existing power lines. It is recognized that the delivery and installation of renal dialysis equipment requires testing and assurance of equipment performance which may be billed for as part of the basic delivery charge. The delivery and installation charge should be itemized, either on the face of the bill or an attached invoice.

If itemized, this amount may be reimbursed to the facility that pays the bill on a lump-sum payment basis.

212. REPLACEMENT

Replacement of equipment which the beneficiary owns or is purchasing is covered in cases of loss, irreparable damage, wear, or when required because of a change in the patient's condition. Expenses for replacement required because of loss or irreparable damage may be reimbursed without a physician's order, when in the judgment of the intermediary the equipment would still fill the patient's medical needs. However, claims involving replacement equipment necessitated because of wear or a change in the patient's condition should be supported by a current physician's order.

Cases suggesting malicious damage, culpable neglect or wrongful disposition of equipment should be reported to the intermediary.

213. REPAIRS

Under normal circumstances, if a facility is in the business of renting or supplying durable medical equipment, it is presumed that there is a margin in the rental or lease charge for the dialysis equipment to cover the costs of repair services. In these cases, neither the facility nor any other party can bill separately for repair services.

In rare situations, a facility may bill separately for repair and maintenance of durable medical equipment provided it can show that its charges for the rental of the machine do not contain a margin to recover the costs of repair and maintenance. The facility must provide adequate detailed cost information to its intermediary so that the intermediary can verify that it has not included repair and maintenance costs in the charge for equipment it leases or rents to home dialysis benficiaries.

215. SUPPLIES FOR PATIENTS DIALYZING AT HOME

Supplies necessary for the effective use of home dialysis equipment are covered under Part B. Conversely, supplies not necessary for the operation of the machine (even though they are necessary for the patient's well being) are generally not covered unless included in a package of the type described in § 215.5. When purchased separately, such items as syringes, alcohol wipes, adhesive tape, alcohol, betadine, and underpads are generally noncovered items

Unless medically justified, the home patient is limited to a maximum of 3 dialyzers per week.

216. COVERED AND NONCOVERED HOME DIALYSIS EQUIPMENT AND SUPPLIES
Following is a list of covered and noncovered home dialysis equipment and supplies. Items used by patients vary as to individaul circumstances, and manufacturers, distributors, and facilities often identify items used for the same purpose differently. This list contains the most frequently used terms, but coverage is not specifically limited to those shown.

216.1. Covered Home Dialysis Equipment.--

A. Dialysate Delivery System.--

1. Pump, recirculating/proportioning
2. Air removal system
3. Flowrate meter
4. Power off alarm
5. Heater and temperature control with alarm
6. I.V. poles, drip chamber holder
7. Pressure gauge
8. Concentrate container/tub
9. Adjustable chairs of the type known as recliners are covered when required as a component of a home hemodialysis delivery station. These chairs are covered because they serve to preserve patient health by allowing rapid manipulation in body position when medical circumstances warrant such changes during dialysis, e.g., when acute hypotension occurs and the patient is in danger of going into shock. However, the reasonable cost of recliner chairs may not include a premium for style or for the capacity to rock, swivel, heat, or vibrate. Claims for recliner chairs will be reviewed to assure that payment is consistent with what is reasonable and medically necessary to serve the intended therapeutic purpose.

   Since the adjustable chair is desirable in the absence of illness or injury, instructions in § 212 should be followed closely when replacement is claimed.

B. Accessory Items.--

1. Blood pump
2. Heparin infusion pump
3. Unipuncture control system
4. Pressure alarm
5. Blood leak detector
6. Air bubble detector
7. Portable conductivity meter
8. Centrifuge Readacrit
9. Sphygmomanometer/Blood pressure apparatus with cuff (and stethoscope)
10. Automatic blood pressure monitors (only when special circumstances exist)

C. Water Purification and Softening Systems Used in Conjunction with Home Dialysis.--

1. Water Purification Systems.--Water used for home dialysis should be chemically free of heavy trace metals and/or organic contaminants which could be hazardous to the patient. It should also be as free of bacteria

as possible but need not be biologically sterile. Since the characteristics of natural water supplies in most areas of the country are such that some type of water purification system is needed, such a system used in conjunction with a home hemodialysis unit is covered under Medicare.

There are two types of water purification systems which will satisfy these requirements: the "deionization" type and the "reverse osmosis" type. Reverse osmosis is a process used to remove impurities from tap water utilizing pressure to force water through a porous membrane. A deionizer removes organic substances, mineral salts of magnesium and calcium (causing hardness), compounds of fluoride and chloride from tap water using the process of filtration and ion exchange. Use of both a deionization unit and reverse osmosis unit in series in order to theoretically provide the advantages of both systems has been determined medically unnecessary since either system can provide water which is pure enough for acceptable use in home hemodialysis. In addition, spare deionization tanks are not covered since they are essentially a precautionary supply rather than a current requirement for treatment of the patient.

Activated carbon filters used as a component of water purification systems to remove unsafe concentrations of chlorine and chloramines are covered when prescribed by a physician.

2. Water Softening Systems.--Except as indicated below, a water softening system used in conjunction with home hemodialysis is excluded from coverage under Medicare as not being reasonable and necessary within the meaning of § 1862(a)(1) of the law. Such a system, in conjunction with a home hemodialysis unit, does not adequately remove the hazardous heavy metal contaminants (such as arsenic) which may be present in trace amounts.

A water softening system may be covered when used to pretreat water to be purified by a reverse osmosis (RO) unit for home peritoneal dialysis where:

a. The manufacturer of the RO unit has set standards for the quality of water entering the RO, e.g., the water to be purified by the RO must be of a certain quality if the unit is to perform as intended,

b. The patient's water is demonstrated to be of lesser quality than required, and

c. The softener is used only to soften water entering the RO unit, and thus, used only for dialysis. (The softener need not actually be built into the RO unit, but be an integral part of the dialysis system.)

3. Developing Need When a Water Softening System is Replaced With a Water Purification Unit in an Existing Home Dialysis System.--The medical necessity of water purification units must be carefully developed when they replace water softening systems in existing home dialysis systems. A purification system may become necessary for a number of reasons. For example, changes in the medical community's opinions regarding the quality of water necessary for safe dialysis may lead the physician to decide the quality of water previously used should be improved, or the water quality itself may have deteriorated. Patients may have dialyzed using only an existing water softener previous to Medicare ESRD coverage because of inability to pay for a purification system. On the other hand, in some cases, the installation of a purification system some time after hemodialysis was initiated may indicate that the system is not medically necessary. Thus, to ensure that the equipment is medically necessary, the facility should submit any supporting documentation with the bill to the intermediary.

216.2 Noncovered Home Dialysis Equipment (Except in initial Set Up*).--

Instruments and Nonmedical Supplies

Tube occluding forceps/clamps
Stopwatch
Thermometer
Tourniquet
Surgical brush
Scissors
Tool kit
Scale

*Physician instruments and nonmedical supplies are not covered unless included in a package charge for dialysis equipment; i.e., they need not be carved out of the initial purchase price and the total need not be reduced. (See also coverage of Centrifuge Readacrit and blood pressure apparatus under "Accessory Items.")

216.3 Covered Home Dialysis Supplies.--Reimbursement may be made for supplies when essential to the effective use of medically necessary durable medical equipment. Medications which may be used in connection with durable medical equipment are generally not covered. Medications fall within the drug restriction and are, therefore, not covered under Part B except for those which cannot be self-administered, are provided as incident to a physician's professional services, and are billed in the name of the physician.

A. Dialyzer.--Synthetic porous membrane or fibers, contained in a supporting structure, through which blood flows for the purpose of eliminating harmful substances, and replacing useful ones when surrounded by dialysate.

Coil, twin coil, single coil
Membrane, Kiil, cuprophan (including blood ports)
Hollow fiber kidney
Cartridge

B. Blood Tubing.--Plastic tube attached to a fistula needle or shunt connector allowing blood to flow to and from the patient and dialyzer.

Blood sets,
Venous/arterial set
Arteriovenous set
Drip Chamber (Bubble-trap holder)

C. Dialysate.--Electrolyte solution containing elements such as potassium, sodium, chloride, etc., surrounding the membrane or fibers allowing exchange of substances with the patient's blood contained in the dialyzer.

Dialysate mixer standard
Diasol concentrate
Hemodialysis concentrate
Bath concentrate
Na, Cl, K solution/electrolyte solution

D. Saline - 30, 250, 500, 1000 cc/ml.--Solution of sodium, chloride, and water used to replace fluid in the body and to prepare the kidney machine for use.

Sodium chloride
Normal saline/isotonic saline
Viaflex
Liquamin sodium
Dextrose

E. Fluid Administration Set.--Plastic tube used for the flow of fluids, such as saline, directly into the dialysis system.

Administrative set
I.V. administration set
Y type administration set
Anesthesia set

F. Fistula Cannulation Set.--Needle or needles used to puncture a vein to provide an access to the patient's blood supply.

Fistula needles/set
#14, 15, 16 ga needles
Unipuncture fistula needle/catheter
Medicut, angiocath
#14, 15, 16 butterfly

G. Shunt Accessories.--Connectors or adapters attached to an artificial, external blood route providing access to the blood supply.

Shunt/universal/teflon connectors
Shunt/universal/teflon adaptors
Silastic tubing

H. Heparin.--A drug used to prevent blood from clotting.

I. Dialysate Testing Supplies.--

Clinitest on other reagents
Quantabs/chloride indicator
Hemastix

J. Blood Testing Supplies.--

Winthrop tubes/Hematocrit tubes
(when used in connection with a centrifuge readacrit)

K. Syringes 3, 5, 10, 20, 30cc*.--

L. Needles 18, 19, 21, 22, 25 guage*.--

M. Sterilizing Agents for Equipment.--

Formaldehyde
Chlorox/Sodium Hypochlorite

N. Cleansing Agents for Equipment.--

Alconex
Haemosol

O. Declotting Equipment.--

Declotting Catheter/Aspirator
Teflon Insert

*Covered only when used to inject heparin into the dialysis system, to adjust the level of blood in the machine, or to flush out shunts and needle lines.

216.4. Noncovered Home Dialysis Supplies*.--

A. Skin/Shunt Preparation Supplies.--Antiseptic solution that inactivates the growth of microorganisms.

Phisohex	Tincture iodine/merthiolate
Betadine	Peroxide
Alcohol wipes	Zephiran

B. Local/Topical Anesthetics.--

Procaine
Xylocaine/Lidocaine
Ethyl chloride

C. Surgical Dressing.--

Sponges, topper, gauze
4 x 4's, 2 x 2's
Telfa pads

*Covered if included in a kit furnished by a nonprovider in which the charges for the covered items in the kit when purchased individually would not exceed the charge for the kit.

D. Tape.--

Dermicel
Micropore
Bandaide clear
Paper
Adhesive

E. Bandages.--

Kling, Kerlix
Stockinette
Ace bandage
Elastoplast

F. Miscellaneous.--

Underpads
Masks
Gloves
Drugs except Heparin

G. Blood Testing Supplies.--

Clotting tubes/capillary tubes
Winthrop tubes/hematcrit tubes (If not used in connection with a centrafuge readacrit)
Red top tubes/vacutainer/chemistry tubes
Pipets
Suction bulb
Culture tubes

H. Surgical Dressings, and Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations.--Surgical dressings are limited to primary dressings, i.e., therapeutic and protective coverings applied directly to lesions (for example, surgical repair of a fistula or shunt) either on the skin or opening to the skin required as the result of a surgical procedure performed by a physician. Surgical

dressings are usually applied first by a physician and are covered under Part B as incident to a physician's professional service. However, dressings may be reapplied by others including the patient or a member of his family. When surgical dressings are obtained by the patient on a physician's order from a supplier, e.g., a drugstore, the surgical dressing is covered under Part B. Dressings required for purposes other than a surgical lesion are not covered.

216.5 Home Dialysis Supply Packages (Kits).--In most instances the items used in home dialysis that are not covered are inexpensive. Consequently, some manufacturers and suppliers include these items in a package of supplies which has a reasonable charge no higher than the charge for the covered items when purchased separately.

If such noncovered items are included in a package with covered items the reasonable charge for Medicare purposes will be the lesser of:

(a) the total of individual reasonable charges for all covered items in the package when purchased separately in comparable quantities,

or

(b) the package charge.

In making this determination, the intermediary will compare the package charge to the charge for covered individual package components from the same supplier. If the total for covered items would entitle purchasers to a quantity discount in the supplier's traditional manner of doing business the discount should be subtracted. Where the supplier provides only packages and has no individual item charges, the intermediary will use its own discretion in selecting charge data from other suppliers for use in making the charge determination.

Approval of a home dialysis supply package (kit) may be made by the intermediary at the time the initial bill for a home dialysis kit is submitted by the facility in order for the intermediary to perform the review necessary to approve a home dialysis kit, an itemized inventory must be attached to the intitial SSA-1483. Once a kit is approved, no itemized inventory is required when the same kit is billed.

IM 216.8 REUSE OF BLOODLINES IN ESRD FACILITIES.

Section 9335(k), of the Omnibus Budget Reconciliation Act of 1986 (OBRA 86), as amended by Section 4036(c) of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), requires that no dialysis facility may reuse dialysis supplies unless the Secretary of Health and Human Services has established protocols for reuse by July 1, 1988 and the facility follows the protocols. Final regulations providing standards and conditions for the reuse and reprocessing of hemodialyzers and dialyzer caps were published in the Federal Register on October 2, 1987. However, protocols for the reuse of bloodlines are not yet available. Therefore, beginning July 1, 1988, Medicare dialysis facilities may not reuse bloodlines.

We wish to emphasize that this prohibition is strictly a matter of conformance with the law. The Public Health Service advises us that there is no imminent public health hazard involved in the reuse of bloodlines, but work on appropriate protocols has not been completed. Reuse of bloodlines is not associated with any increased risk of hepatitis B virus (HBV) infection in either patients or staff members or with the occurrence of pyrogenic reactions or septicemia in patients.

In the event that any component of the home dialysis kit changes or there is a substantital price change of any component, an itemized inventory of the revised kit must be submitted with the first SSA-1483 bill for the revised kit for the intermediary's review for allowability.

Following is an example of a package of home dialysis supplies for a two-month period. The supplier's charge of $705 for the package in this instance is less than the sum of charges for individual covered components if purchased separately and, hence, is the reasonable charge.

Example of a Package of Home Dialysis Supplies

Item	Quantity	Individual Unit Price	Charge If Billed Separate
Coil	4 Case/6	$ 99.80/Case	$399.20
Syringe 3cc 25g. 5/8"	1/2 Box/100	8.00/Box	4.00
Venous Set	2 Case/12	22.00/Case	44.00
Arterial Set	2 Case/12	22.00/Case	44.00
Syringe 10cc 20g. 1-1/2"	2 Box/50	Not Covered	-----
Dialysate	6 Case/4	12.00/Case	72.00
Saline 1000cc - viaflex	6 Case/12	18.96/Case	113.76
Administration Set	1/2 Case/48	35.00/Case 48	17.50
Adhesive Tape 1/2"	2 Rolls	Not Covered	-----
Oversponges 4 X 3	3 Trays/25	Not Covered	-----
Alcohol Wipes	2 Box/100	Not Covered	-----
Travenol Fistula Needles	1 Case/50	20.00/Case 50	20.00
Heparin 10000	12 Vials	30.00/Box 25	14.40
Bandaids	1 Box/100	Not Covered	-----
Alcohol	2 Pints	Not Covered	-----
Betadine	1 Pint	Not Covered	-----
Underpads	50	Not Covered	-----
Procaine 1%	1 Vial	Not Covered	-----
		Total Covered Supplies If Billed Separately	$728.86
		Package Charge	705.00
		Reasonable Charge	705.00

General Exclusions From Coverage

217. GENERAL EXCLUSIONS
No payment can be made under the health insurance program for certain items and services as indicated in the following sections (§§ 218 - 226).

218. SERVICES NOT REASONABLE AND NECESSARY
Items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the patient's condition are not covered.

219. NO OBLIGATION TO PAY FOR OR PROVIDE SERVICES
Program payment may not be made for items or services which neither the beneficiary nor any other person or organization has a legal obligation to pay for or provide. This exclusion applies where items and services are furnished free of charge without regard to the individual's ability to pay, and without expectation of payment from any source, such as free X-rays or immunizations provided by health organizations.

However, Medicare coverage is not excluded where a third party, rather than the patient is obligated to pay for or provide the items and services. Furthermore, reimbursement is not precluded merely because a provider waives its charge in the case of a particular patient or for a class of patients. The waiver of charges for some patients does not impair the right to charge others, including Medicare patients. The determinative factor is the reason the particular individual is not charged.

The following sections illustrate the applicability of this exclusion to various situations involving services furnished by nongovernmental providers. (For a discussion of services paid for by a government instrumentality, see § 220.2.)

219.1. Indigency.--This exclusion does not apply where items and services are furnished an indigent individual without charge because of his inability to pay, if the provider bills other patients to the extent that they are able to pay.

B. Statutory Exceptions.--The exclusion of items and services paid for by a governmental entity does not apply in the following situations; therefore, payment may be made under Medicare where:

1. The items or services are furnished under a health benefits or insurance plan established for employees of the governmental entity;

2. The items or services are furnished under one of the titles of the Social Security Act (such as medical assistance under title XVI or XIX).

C. Exceptions Approved by the Secretary.--The Secretary of Health, Education, and Welfare is authorized by law to specify additional exceptions to this exclusion. The Secretary has approved Medicare payment for items or services which are paid for by a State or local governmental entity and furnished an individual as a means of controlling infectious diseases or because the individual is medically indigent.

220.4. Illustrations of Exclusions of Services Covered by Various Governmental Programs.--

A. Veterans Administration.--Services furnished without charge by a VA facility are excluded from coverage under Medicare. In addition, the fact that a beneficiary is eligible to have services furnished by private sources paid for by the VA precludes payment for them under Medicare. It will generally be advantageous for health insurance beneficiaries to have services paid for under a VA program where possible since the VA has no deductible or coinsurance requirements.

B. Government Research Grants.--A beneficiary who would be eligible to have his care paid for by a governmental research grant can receive benefits under title XVIII if the facility charges those patients who have Medicare or other insurance. Where a provider claims benefits under title XVIII, it may not accept research grant funds for the services in question, except to the extent of the deductible and coinsurance amounts.

C. Vocational Rehabilitation Agencies.--Under the vocational rehabilitation programs of the various States, vocational training and services are provided to handicapped persons who qualify under State law. Where items or services are furnished or paid for by a State VR agency, title XVIII benefits are payable only if the agency makes services available without cost because of the individual's medical indigency or as a means of controlling infectious diseases.

D. State or Local Health Department Clinics.--Many State or local health departments operate outpatient clinics. Services rendered by such clinics free of charge because of the individual's indigency or as a means of controlling infectious diseases (e.g., city-operated charity clinics) are covered under title XVIII.

E. Civilian Health and Medical Program of the Uniformed Services (Military Medicare).--This program provides both hospitalization and outpatient care in civilian facilities for spouses and children of active duty members of the uniformed services, retired servicemen, and spouses and children of retired and deceased members of the uniformed services.

Retired members of the uniformed services, their spouses and children, or the spouses and children of deceased members, who are not entitled to Part A benefits but who are enrolled in Part B may not receive military Medicare benefits for services covered under Part B, except to the extent that benefits are not payable under Part B. Dependents of active duty members of the uniformed services are not governed by the above rules. They have the option of electing to claim benefits under either military Medicare or title XVIII. If benefits are paid under military Medicare, title XVIII benefits are not payable for the same services, except for charges not covered under military Medicare, e.g., the military Medicare deductible and coinsurance amounts.

F. Active Duty Servicemen.--In limited circumstances servicemen on active duty may have care in civilian facilities paid for by the armed services. Except for emergency services, prior approval is generally required before such payment can be made. Services furnished pursuant to such approval and services paid for or expected to be paid for are not reimbursable under title XVIII.

221. SERVICES NOT PROVIDED WITHIN THE UNITED STATES

Services (except for certain inpatient hospital services and related physicians and ambulance services in specified situations) which are not provided within the United States are not covered. The United States includes the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

222. SERVICES RESULTING FROM WAR

Items and services which are required as a result of war, or of an act of war, occurring after the effective date of the patient's current coverage are not covered.

223. ITEMS AND SERVICES COVERED UNDER A WORKERS' COMPENSATION LAW

Payment under Medicare may not be made for any items and services to the extent that payment has been made or can reasonably be expected to be made for such items or services under a workers' compensation law or plan of the United States or a State.

224. ROUTINE SERVICES AND APPLIANCES

Routine physical checkups include (a) examinations performed without relationship to treatment or diagnosis for a specific illness, symptom, complaint, or injury, and (b) examinations required by third parties such as insurance companies, business establishments, or Government agencies.

Routine physical checkups; eyeglasses, contact lenses, and eye examinations for the purpose of prescribing, fitting, or changing eyeglasses; eye refractions by whatever practitioner and for whatever purpose performed; hearing aids and examinations for hearing aids; and immunizations are not covered.

225. CHARGES IMPOSED BY IMMEDIATE RELATIVES OF THE PATIENT OR MEMBERS OF HIS HOUSEHOLD

A. General.-- Payment may not be made for expenses which constitute charges by immediate relatives of the beneficiary or by members of his household. The intent of this exclusion is to bar Medicare payment for personal services of physicians or suppliers which would ordinarily be furnished free of charge beacuse of the relationship of the beneficiary to the person imposing the charge. Payment may be made, however, for reasonable charges imposed on such individuals by a physician or supplier to recover out-of-pocket expenses he has incurred in furnishing covered items or supplies, e.g., expenses for covered drugs and biologicals, prosthetic devices, etc. In such cases, the charge may not exceed the physician's or supplier's actual out-of-pocket costs.

B. Services of Providers and Provider-Based Physicians.-- This exclusion applies only to services reimbursed on a charge basis and does not apply to provider services of group practice prepayment plans which are reimbursed for their costs rather than charges. Thus, reimbursement may be made for covered services furnished by a provider to an owner of the institution or to an immediate relative of an owner, or a member of an owner's household.

Reimbursement may not be made, however, for the professional component of services of provider-based physicians furnished to an immediate relative of the physician or to a members of the physician's household. Since the personal services of provider-based physicians are billed on a charge basis, they would be subject to this exclusion whether the bill is submitted by the physician or, with his authorization, by the provider.

C. Immediate Relative.-- The following degrees of relationship are included within the definition of "immediate relative": (1) Husband and wife; (2) natural parent, child, and sibling; (3) adopted child and adoptive parent; (4) stepparent, setpchild, stepbrother, and stepsister; (5) father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, and sister-in-law; (6) grandparent and grandchild.

NOTE: It has been deemed for program purposes that a brother-in-law or sister-in-law relationship does not exist between a physician (or supplier) and the spouse of the wife's/husband's brother or sister.

A father-in-law or mother-in-law relationship does not exist between a physician and his spouse's stepfather or stepmother.

D. Members of the Patient's Household.-- These are persons sharing a common abode with the patient as a part of a single family unit, including those related by blood, marriage or adoption, domestic employees and others who live together as part of a single family unit. A mere roomer or boarder is not included.

E. Charges by Professional Corporation or Business Organization Such as Supplier and Clinic.--Charges imposed by a medical group, clinic, or supplier which is not a corporation are, in effect, imposed by the owner or owners of the business. Thus, this exclusion applies where such a firm is owned by a sole proprietor who bears one of the excluded relationships to the patient. In the case of a partnership, the exclusion applies only where all of the partners bear one of the excluded relationships to the patient. Charges imposed by a corporation are not subject to this exclusion except in the case of charges imposed by a professional corporation for items or services furnished (1) by an owner who bears one of the excluded relationships to the patient or (2) by an employee under the supervision of a related owner. "Professional corporation" means a corporation that is operated solely for the purpose of conducting the practice of medicine, osteopathy, dentistry, podiatry, optometry, or chiropractic. Only members of the profession can own stock in a professional corporation. Any physician or group of physicians which is incorporated constitutes a professional corporation. (Generally, physicians who are incorporated identify themselves by adding letters such as P.C. or P.A. after their title.)

The exclusion does not apply to charges imposed by a corporation other than a professional corporation, regardless of the patient's relationship to any of the stockholders of the corporation or to the person who furnished the service.

226. PERSONAL COMFORT ITEMS

Items which do not contribute meaningfully to the treatment of an illness or injury or the functioning of a patient's condition are not covered.

227 LIMITATION ON PAYMENT FOR SERVICES REIMBURSABLE UNDER AUTOMOBILE MEDICAL, NO FAULT, OR ANY LIABILITY INSURANCE

Payment may not be made under Medicare for otherwise covered items and services to the extent that payment has been or can reasonably be expected to be made under automobile medical or no fault insurance or under any liability insurance.

Coverage of Transplantation (Limited to Participating Hospitals)

230. COVERAGE--GENERAL

During the development of Medicare policies and procedures necessary to effectively implement the chronic renal disease provisions of the 1972 Amendments to the Social Security Act, special attention was necessarily given to the policies concerning the coverage and reimbursement of renal transplant services. Since renal transplantation is a principal form of treatment available to patients with end-stage renal disease, it was evident that the Medicare program should adopt policies which would contribute to the support of this method of treatment by providing an equitable means of reimbursement for the variety of medical services that are required to support a quality transplant program.

While there were many issues to consider in accomplishing this objective; there were two principal areas of concern. First, it was necessary to insure that Medicare would pay its share of the costs of organ procurement recognizing that in live donor organ procurement there would be a considerable amount of medical costs incurred in evaluating potential donors prior to the possible selection of a donor, and that in the cadaver organ procurement program not all organs excised would eventually be transplanted. Second, an equitable means had to be developed for covering and reimbursing necessary medical services provided to potential donors and recipients, recognizing that in some situations these services would be provided prior to the effective date of the potential transplant recipients Medicare entitlement.

Therefore, in order to determine costs of Medicare covered services which are normally provided in preparation for a transplant and for kidneys acquired for the purpose of providing Medicare beneficiaries with renal transplants and to encourage the consideration of this treatment modality; i.e., allowing beneficiaries who are acceptable

candidates for transplantation the opportunity to be transplanted irrespective of economic factors, the concept of the kidney acquisition cost center was developed. In addition to supporting the above objectives, the use of a kidney acquisition cost center also provides the mechanism for reviewing the costs of services provided between hospitals under arrangements. It also provides the mechanism to make more current reimbursement for some costs which, using preexisting reimbursement policy, could not be reimbursed by the program until they could be added to a billable service which is generated by a participating hospital. (Since non-hospital renal dialysis facilities are not involved with renal transplantation, extensive guidelines relating to transplantation are not being provided. Questions not covered in the following sections should be referred to your intermediary).

231. COVERAGE OF SERVICES INVOLVING LIVING DONOR TRANSPLANTS

After end-stage renal disease is diagnosed, one of the first actions taken by many physicians is determining the suitability of the patient for transplantation. If it appears that the patient is a suitable transplant candidate, a live donor transplant is normally considered first because of its relatively high degree of success in comparison to a cadaveric transplant. Whether one or multiple potential donors are available, the following is a general description of the usual course of events which transpire in preparation for a live-donor transplant.

First, potential donors are identified. Generally, potential donors include only parents, brothers and sisters, or children. Those who are willing and medically able to donate a kidney to the recipient are first tested to determine whether they are of the same blood type as the recipient. After blood-typing, the recipient and the donors are tissue typed. Only those candidates with blood and tissue types similar to the recipient are considered further. After tissue typing, those donors who are medically suitable are evaluated based on physical, psychological and social factors. Those potential donors who remain after the above testing may be hospitalized for further evaluation using procedures not appropriately performed on outpatients. These procedures may include intravenous urography and renal arteriography. Hospitalization for 2 days appears to be the average stay for these services.

If the results of the above tests identify several suitable donors, the most suitable donor is selected and arrangements are made for the transplant. At such time, the donor and recipient will enter the hospital to undergo the excision and transplantation, respectively. Where tests do not identify an acceptable living donor, the patient will generally be considered for a cadaveric transplant and placed on hemo- or peritoneal

dialysis, if this has not already proved necessary. Also, if the ultimate goal is transplantation, the patient would be registered with a kidney transplant registry.

232. COVERAGE OF SERVICES INVOLVING CADAVERIC TRANSPLANTS

Where there is no suitable living donor, a patient with renal failure may be considered for a cadaveric transplant. In such cases the services provided to recipients of "live donor kidneys," i.e., tissue typing and other related tests, are also provided to potential recipients of cadaver kidneys. However, because a kidney may not be available for a long period of time, it is expected that additional services will be provided in the form of direct physician care for the patient's renal condition, and certain tests will normally be performed on a regular basis to allow the physician to have current information regarding the status of the patient and his suitability for transplant. In addition, mixed lymphocyte cultures are prepared whenever a kidney is procured which may suit the recipient. The number of such tests performed depends directly on the number of kidneys which become available for transplant.

233. COVERAGE OF PRE-TRANSPLANT INPATIENT SERVICES

The following rules apply to kidney transplant inpatient medical evaluations when the kidney recipient has Medicare entitlement or is in the pre-entitlement period. The pre-entitlement period is that period during which services are furnished in anticipation of a transplant after the patient has been diagnosed to have end-stage renal disease, but prior to such patient's actual Medicare entitlement. If the potential kidney recipient does not have entitlement or is not in the pre-entitlement period, any service rendered to the kidney recipient or to the related living donor for kidney transplant medical evaluations will not be covered by the Medicare program.

233.1 Living Donor Evaluation.--When a living donor is admitted to a hospital (before admission for excision of the donor kidney for transplant) for a medical evaluation in anticipation of a kidney donation, all hospital costs and the costs of the physician services applicable to the medical evaluation are considered kidney acquisition service costs. As such, the hospital and the physician charges will be included in Medicare costs.

When the living donor subsequently enters the hospital for the actual transplant, the hospital costs of services rendered to the donor will continue to be treated as kidney acquisition service costs. However,

during the kidney transplant inpatient stay and during any subsequent donor inpatient stays resulting from a direct complication of the organ donation, the physicians services are not considered kidney acquisition services, and are not included in Medicare costs.

233.2. Kidney Recipient Admitted for Transplant Evaluation.--When a recipient is specifically admitted to a hospital (before the admission for the actual transplant) for a medical evaluation for an anticipated kidney transplant, all hospital costs and the costs of physician services applicable to the anticipated transplant are considered kidney acquisition service costs. As such, the hospital and the physician charges will be included in Medicare costs.

233.3 Kidney Recipient Evaluated for Transplant During an Inpatient Stay.--When a recipient is specifically admitted to a hospital for a medical reason other than in anticipation of a transplant, but during the stay, a medical evaluation for an anticipated kidney transplant is performed, all hospital costs and the costs of the physician services applicable to the medical evaluation are treated the same as the services above. However, all hospital and physician services applicable to the non-transplant related services (i.e., related to the medical services for which the patient was actually admitted) may only be billed to the Medicare program if the recipient has actual Medicare entitlement.

233.4. Kidney Recipient Admitted for Transplantation and Evaluation.--When the medical evaluation for a transplant is performed on the recipient or the living donor during the same inpatient stay in which the actual transplant occurs, all such services will be billed and the costs will be accumulated in the normal manner. For example, all hospital services rendered to the donor will be considered kidney acquisition services. However, all physician services rendered to the living donor and all hospital and physician services rendered to the recipient will be billed in the same manner as any other inpatient services on the account of the recipient.

services must be furnished directly by the sponsoring CAPD facility (see paragraph A below). Home dialysis support services may be furnished in the home or in the facility. While usual support services are provided or arranged for by the facility, they may also be provided by a physician or under a physician's direct personal supervision.

A. Home Dialysis Support Services.--The full range of home dialysis support services required by home CAPD patients is covered. In addition to the general support services furnished to home hemodialysis patients, support services specifically applicable to CAPD patients include but are not limited to: (1) changing the connecting tube (also referred to as an administration set), (2) watching the patient perform CAPD and assuring that it is done correctly, and reviewing for the patient any aspects of the technique he may have forgotten, or informing the patient of modifications in apparatus or technique, (3) documenting whether the patient has or has had peritonitis that requires physician intervention or hospitalization (unless there is evidence of peritonitis, a culture for peritonitis is not necessary), (4) inspection of the catheter site.

The CAPD support services must be furnished by the sponsoring CAPD facility periodically (not less than once every 90 days) in accordance with the certification requirements referred to in § 240.1. These services will usually be furnished during a periodic followup visit, but they may be furnished at separate times. They may be furnished in the facility or in the home.

Normally, the changing of the connecting tube is performed in the facility, and all of the other CAPD support services can be performed at the same time. However, sometimes a member of the facility's staff may go to the patient's home to observe the patient's CAPD technique, take blood samples, etc. In any case, each of the CAPD support services may be covered routinely at a frequency of once per month.

Because these services must be furnished periodically by the sponsoring CAPD facility, any claims for additional support services furnished more frequently than monthly (whether by the sponsoring CAPD facility of under an agreement or arrangement) must be developed carefully for medical necessity.

B. Supplies.--All supplies required to perform CAPD are covered. These include start-up durable supplies (whether or not they are part of a start-up kit) such as weight scales, sphygmomanometer, IV stand, and dialysate heaters; and consumable and disposable supplies such as dialysate, tubing and gauze pads.

C. Drugs and Biologicals.--Drugs and biologicals such as blood may be covered in the home dialysis setting only if the "incident to a physician's services" critera are met. Normally, a physician is not in the patient's home when the drugs or biologicals are administered, and therefore, generally drugs and biologicals are not covered in the home setting.

D. Laboratory Tests.--The following lab tests are covered routinely at the frequencies specified below if furnished to a CAPD patient in a certified setting. Any test furnished in excess of this frequency, or any test furnished that is not listed here is covered only if there is documentation of its medical necessity. A diagnosis of ESRD alone is not sufficient medical documentation. The nature of the illness or injury (diagnosis, complaint or symptom) requiring performance of any other tests not listed here must also be present on the form.

1. Laboratory Tests for CAPD Covered Routinely and Included Under the Composite Rate

Monthly	
BUN	Total Protein
Creatinine	Albumin
Sodium	Alkaline Phosphatase
Potassium	LDH
CO2	SGOT
Calcium	Hct
Magnesium	Hgb
Phosphate	Dialysate Protein

2. Laboratory Tests for CAPD Covered Routinely and Separately Billable

Every 3 Months
WBC
RBC
Platelet count

Every 6 Months	
Residual renal function	Bone mineral density
24 hour urine volume	MNCV
Chest X-ray	EKG

(See §207.3 for laboratory tests rendered to hemodialysis, intermittent peritoneal dialysis (IPD) and continuous cyclical peritoneal dialysis (CCPD) patients.)

E. Equipment and Water Testing.--CAPD does not require the use of any equipment or testing of water because the dialysate is prepared and delivered by the manufacturer. Therefore, neither a dialysis machine nor water testing or water treatment are covered for CAPD patients. Patients changing from another form of home dialysis to CAPD may have their claims for rental or lease-purchase of home durable medical equipment reimbursed up to 3 months after completing the CAPD training course.

245. COVERAGE OF HOME DIALYSIS UNDER TARGET RATE REIMBURSEMENT

Target rate reimbursement is an optional method of Medicare reimbursement for the cost of furnishing to self-care home dialysis patients all necessary home dialysis medical supplies, equipment, and supportive services, including the services of qualified home dialysis aides. Under this method payments are made on the basis of an annually determined prospective per dialysis treatment target reimbursement rate. Any certified end-stage renal disease (ESRD) facility may select this option by entering into a special agreement with the Health Care Financing Administration (HCFA).

The target rate payment is a comprehensive payment for all of the home peritoneal and home hemodialysis items and services furnished to the facility's home dialysis patients. At this time, items and services furnished for continuous ambulatory peritoneal dialysis (CAPD) will not be included under the target rate reimbursement system. Reimbursement for CAPD will continue as before on a fee-for-service basis even for facilities that have elected the target rate option.

The law establishing target rate reimbursement for home dialysis has an effective date of April 1, 1979 (Section 6 of P.L. 95-292). Accordingly, this reimbursement option is available retroactive to that date subject to the requirements specified in the agreement.

The target rate reimbursement system is distinguished from the present system of reimbursing home dialysis in two respects. First, in addition to all of the home dialysis items and services already covered under the program, it also includes payment for the costs of furnishing home dialysis aides. Second, it is intended to be an incentive system in that a facility has the right to retain the difference between its actual costs for covered supplies, equipment, and services and the target rate payment.

245.1 Definitions

A. Home Dialysis Equipment.--Home dialysis equipment includes all of the medically necessary home dialysis equipment prescribed by the attending physician including (but not limited to) artificial kidney and automated peritoneal dialysis machines, and support equipment.

B. Support Equipment.--Support equipment is equipment used in conjunction with the basic dialysate delivery system. Such equipment includes (but is not limited to) pumps, such as blood and heparin pumps, alarms, such as bubble detectors, water purification equipment used to improve the quality of the water used for dialysis, and adjustable dialysis chairs.

C. Support Services.--Support services include (but are not limited to): 1) periodic monitoring of a patient's adaptation to home dialysis and performance of dialysis; 2) visits by trained technical personnel made in accordance with a plan prepared and periodically reviewed by a professional team which includes the individual's physician; 3) unscheduled visits made on an as-needed basis, e.g., assistance with difficult access situations; and 4) providing, installing, repairing, testing and maintaining home dialysis equipment including appropriate water testing and treatment.

D. Installation.--Installation includes (but is not limited to) the identification of any minor plumbing and electrical changes required to accomodate the equipment, the ordering and performing of these changes, delivery of the equipment, and its actual installation (i.e., hooking-up), as well as any necessary testing to assure proper installation and function.
Minor plumbing and electrical changes include those parts and labor required to connect the dialysis equipment to plumbing and electrical lines that already exist in the room where the patient will dialyze. Medicare does not cover wiring or rewiring of the patient's home, or installing any plumbing to the patient's home or to the room of the home where the patient will dialyze.

E. Maintenance.--Maintenance includes (but is not limited to) travel to the patient's home, or if needed, transportation of the equipment to a repair site, the actual performance of the maintenance, or repair and all necessary parts. With respect to water purification equipment, maintenance includes replacing the filter on a reverse osmosis device, regenerating the resin tanks on a deionization device, and the chemicals used in a water softener, as well as periodic water testing to assure proper performance. Routine maintenance tasks customarily performed by a patient are not covered services except for the cost of parts involved in this maintenance furnished by the facility to a patient.

F. Home Dialysis Aide (Home Aide).--A person who meets the qualifications set by the facility and all applicable State and local laws to assist self-care home dialysis ESRD patients in the performance of home dialysis.

G. Supplies.--Supplies include all durable and disposable items and medical supplies necessary for the effective performance of a patient's dialysis. Supplies include, but are not limited to, dialyzers, forceps, sphygmomanometer with cuff and stethoscope, scales, scissors, syringes, alcohol wipes, sterile drapes, needles, topical anesthesias, and rubber gloves.

H. Routine ESRD Related Laboratory Tests.--Routine laboratory tests include those tests and their frequencies as set forth in Section 207.1A.

245.2 Coverage.--The target rate includes payment for all home dialysis supplies, equipment, and support services required for home dialysis. The coverage requirements under the target rate reimbursement option are the same as for home dialysis items and services under the general program except that the services of home dialysis aides are also included. A facility choosing this reimbursement option is required to furnish, either directly or under arrangements, all the covered items and services, as medically necessary, to all its home dialysis patients. In choosing this option a facility must agree to include all of its home dialysis patients, with the exception of CAPD patients, under target rate reimbursement and not restrict the availability of home dialysis services. CAPD patients are excluded from this provision because the home dialysis target reimbursement rate is designed to cover a broader range of personnel and equipment than is normally used in performing CAPD.

A. Items and Services Included under the Target Rate.--All items and services included under the target rate must be furnished by the facility, either directly or under arrangements, to all of its home dialysis patients. These include:

1) medically necessary home dialysis equipment and home dialysis support equipment;

2) home dialysis support services including the delivery, installation, maintenance, repair and testing of home dialysis equipment and home support equipment;

3) where necessary, the services of trained home dialysis aides;

4) purchase and delivery of all necessary home dialysis supplies; and

5) routine ESRD related laboratory tests.

(See Section 245.1 Definitions, for specific meanings of these items.)

B. Home Aides.--The services of home aides are not reimbursable on a fee-for-service basis under the Medicare program. However, reimbursement for these services is included under the target rate. In fact, a facility that has elected the target rate method must furnish a qualified home aide whenever one is necessary. The facility determines the qualifications of an aide, and makes the initial determination as to when an aide is necessary. This must be done according to the minimum criteria approved by HCFA for home dialysis aides that the facility submits pursuant to its agreement. (See Section 407.3A for further discussion of these criteria).

C. Frequency of Home Dialysis Sessions.--Both home hemodialysis and home peritoneal dialysis are covered under the target rate. CAPD is not covered under the target rate.

1. Hemodialysis

The usual pattern of home hemodialysis consists of three sessions weekly, and these may be covered routinely. If the facility bills for any sessions in excess of this frequency, the bills must be accompanied by medical justification acceptable to the intermediary.

2. Peritoneal Dialysis

Home peritoneal dialysis sessions are covered routinely at the same frequency as home hemodialysis described above. However, the pattern of peritoneal dialysis may vary in which case an equivalence is established between peritoneal and hemodialysis as described in Section 407.1C. If the facility bills for any sessions in excess of this frequency, the bills must be accompanied by medical justification acceptable to the intermediary.

D. Infacility Backup Dialysis.--The facility must explain why any infacility backup dialysis sessions (furnished on either an inpatient or outpatient basis) are furnished to home dialysis patients who are covered under the target rate. If a backup session is furnished because of a failure to furnish any of the required items or services referred to in paragraph A, then it will be covered only to the extent of a home dialysis session and reimbursed at the facility's target rate. If the backup dialysis is furnished by an institution other than the home patient's target rate facility, then the target rate facility must assume financial liability for any cost or charge in excess of the facility's target rate except where the patient is travelling away from home (see paragraph E below).

Under the circumstances described above, the backup dialysis will be counted as a home dialysis session for the purpose of frequency of sessions routinely covered (see paragraph C above).

E. Coverage of Infacility Dialysis Sessions Furnished to Patients Who are Travelling.—Patients who are normally home dialysis patients supported by a target rate reimbursement facility may be dialyzed by another facility on an infacility basis when travelling away from home. These services may be reimbursed as any other infacility dialysis furnished by that facility.

F. Physician's Services.--

1. Initial Method (physician reimbursement method no. 1 as defined in 42 CFR 405.542(a)). - Any services furnished to a target rate facility's home patients by a physician that are included as home dialysis support services under paragraph A can only be covered under the target rate. Because payment for these services is already included in the target rate, reimbursement to physicians would be duplicative and therefore is not permitted. Any services furnished to target rate patients by a physician that are not included under paragraph A, are only covered as physician services and must be billed by the physician directly to the program separate from the target rate.

Any services furnished to target rate patients by a physician that are not included under paragraph A, are only covered as physician services and must be billed by the physician directly to the program separate from the target rate.

2. Alternative Method (physician reimbursement method no. 2 as defined in 42 CFR 405.542(b)). - Reimbursement to physicians under the alternative method is unaffected by the target rate. Because the alternative method payment is for physician services and the target rate payment is for facility services, they are not considered to be duplicative. Therefore, the monthly alternative method payment to a physician for home patients is the same whether the patients are supported by a target rate facility or not, and all rates pertaining to the alternative method apply as usual.

250 LIMITATION ON PAYMENT FOR SERVICES TO INDIVIDUALS ENTITLED TO BENEFITS SOLELY ON THE BASIS OF END STAGE RENAL DISEASE WHO ARE COVERED BY EMPLOYER GROUP HEALTH PLANS

250.1 General.—Medicare benefits are secondary to benefits payable under an employer group health plan (EGHP) in the case of individuals entitled to benefits solely on the basis of end stage renal disease (ESRD) (see §105.3), during a period of up to 12 months, which is defined in §§250.4 and 250.5. Medicare is secondary during this period even though the employer policy or plan contains a provision stating that its benefits are secondary to Medicare's, or otherwise excludes or limits its payments to Medicare beneficiaries.

Under this provision, renal dialysis facilities (RDF's) must bill the EGHP first for services rendered on or after January 21, 1988. Medicare secondary benefits are payable in accordance with §250.10 if:

- the plan payment is less than your charges for Medicare covered services,
- the plan payment is less than the gross amount payable by Medicare, and
- you do not accept, and are not obligated to accept, the EGHP payment as payment in full.

This provision applies to all Medicare covered items and services furnished to beneficiaries who are in a 12-month period, including services for non-ESRD treatment and services required by kidney donors in cases of transplantation. (See §233.1.) Consider the possible application of this limitation when processing claims for items or services furnished to ESRD beneficiaries who are in their first year of entitlement.

NOTE: These instructions do not apply to beneficiaries entitled to Medicare because of age 65 or disability.

250.2 Definitions.—

A. Employer.—The term "employer" means, not only individuals and organizations engaged in a trade or business, but organizations exempt from income tax, such as religious, charitable, and educational institutions as well as the governments of the United States, the States, Puerto Rico, Guam, the Virgin Islands, American Samoa, the Northern Mariana Islands and the District of Columbia, including their agencies, instrumentalities and political subdivisions. For purposes of the ESRD secondary payer provision the term "employer" is defined without regard to the number of employees.

B. Employer Group Health Plan or Employer Plan. —These terms mean any health plan that is of, or contributed to by, an employer; and that provides medical care, directly or through other methods such as insurance or reimbursement to current or former employees, and/or their families. It includes the Federal Employees Health Benefits

program but not the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). "Employee pay all" plans, i.e., group health plans under the auspices of an employer which do not receive any contributions from the employer, also meet the definition of EGHP.

Assume in the absence of evidence to the contrary, that any health plan (including a union plan) in which a beneficiary is enrolled because of the current or former employment of the beneficiary or of a member of the beneficiary's family meets this definition.

C. Secondary— The term "secondary," when used with respect to Medicare payment, means that Medicare is the residual payer to all employer group health plans under which the Medicare beneficiary is covered and will not pay for any expenses that are reimbursable by any such plan or plans. Consider the workers' compensation exclusion (§223) and no fault and liability insurance provisions (§227) in determining the extent of Medicare's liability as a residual payer since in some cases there may be a primary insurer in addition to the EGHP. (See §250.9C.)

D. Coordination Period.—The term "coordination period" means a period of up to 12 months determined in accordance with §§250.4 and 250.5 during which Medicare benefits are secondary to benefits payable under employer group health plans.

250.3 Retroactive Application.—If the intermediary notifies you, or you learn from other sources that an employer plan may be primary payer for services for which Medicare paid primary benefits, take the following actions:

- o ascertain whether there is EGHP coverage and if so, the name and address of the EGHP , if that information is not annotated on the claim,
- o check your records and ascertain whether Medicare paid primary benefits for other services rendered during a coordination period for which an EGHP may be primary,
- o notify the intermediary of the results of your development efforts.

This information is necessary for Medicare to determine its proper payment. If the employer plan pays or has already paid you for all or part of the services, submit a corrected bill to the intermediary along with the employer plan's explanation of benefits (EOB). The intermediary will recoup from you the amount of Medicare benefits paid in excess of any amount it is obligated to pay as secondary payer.

250.4 Determining the Months During Which Medicare May Be Secondary Payer.— Medicare is secondary to EGHPs for items and services furnished during a period of up to 12 consecutive months which begins with the earlier of:

- o the month in which a regular course of renal dialysis is initiated, or
- o in the case of an individual who receives a kidney transplant, the first month in which the individual became entitled to Medicare.

NOTE: In the extremely rare case of an untimely application by an individual who receives a transplant, the 12-month period could begin with the first month in which the individual would have been entitled to Medicare benefits if a timely application had been filed. (See §105.3 for the earliest possible month of entitlement in transplant cases.) It is not necessary to consider this possibility absent a specific indication, e.g., information in file that the transplant occurred before the first actual month of entitlement. If further development is required contact the Social Security office.

When the 12-month period begins before the month the individual becomes entitled to Medicare, Medicare pays secondary benefits for the portion of the period during which the individual is entitled to Medicare benefits. This is the coordination period. (See § 250.2D.) Since Medicare entitlement usually begins with the third month after the month in which the individual starts a regular course of dialysis, Medicare is usually the secondary payer for the first 9 months of an individual's entitlement. However, for individuals who undertake a course in self-dialysis training or who receive a kidney transplant during the 3-month waiting period, Medicare may be the secondary payer for up to the first 12 months of the individual's entitlement.

The following examples illustrate how to determine the number of months in which Medicare pays secondary benefits for various situations in which benefits are payable by an EGHP:

(1) Individual Became Entitled to Medicare After a Waiting Period.--Janice started a regular course of dialysis in October 1986. The 12-month period begins in October 1986 (the month in which Janice started a regular course of dialysis) and the waiting period consists of October, November and December 1986. Medicare is secondary payer from January through September 1987.

Peter started a regular course of dialysis in January 1987 and was hospitalized and received a kidney transplant in March 1987. The 12-month period begins with January 1987. The kidney transplant cuts short the dialysis waiting period so that Peter becomes entitled in March 1987. Medicare is secondary payer from March through December 1987.

(2) Individual Became Entitled to Medicare Without a Waiting Period.--In October 1987, John began a regular course of dialysis. In December 1987, he began a course of self-dialysis training. Since the self-dialysis training course was initiated during the first 3 months of dialysis, he is exempt from the waiting period and becomes entitled as of October 1987, the first month of dialysis. In this situation, the first month of entitlement coincides with the beginning of the 12-month period. Thus, the coordination period extends from October 1987 through September 1988. Medicare is secondary payer during this period.

250.5 Effect of Changed Basis for Medicare Entitlement.--If the basis for an individual's entitlement to Medicare changes from ESRD to age 65 or disability, the coordination period terminates with the month before the month in which the change is effective.

250.6 Subsequent Periods of ESRD Entitlement.--If an individual has more than one period of entitlement based solely on ESRD, a coordination period will be determined for each period of entitlement in accordance with §§ 250.4 and 250.5.

250.7 Identification of Cases in Which Medicare May Be Secondary to Employer Group Health Plans.--Investigate cases in which information available to you (e.g., the beneficiary's Medicare card) indicates that the beneficiary is entitled to Medicare based on ESRD for 1 year or less at the time the services were rendered to ascertain whether the services were rendered during the 12-month period described in §§250.4 and 250.5. Determine whether the services were rendered in the 12-month period by checking your own records; e.g., information contained on the HCFA Form 2728 or, if the potential Medicare payment is $50 or more, with other providers or facilities, or the beneficiary's physician, if necessary, to determine the date the individual started a regular course of dialysis or the date the individual received a kidney transplant (or entered a hospital to receive a transplant). If the individual is in the 12-month period, ask the beneficiary if he/she is insured under any health insurance plan which provides coverage through the employer or through a union. If the response is yes, ask for the name and address of the plan and the beneficiary's identification number.

If the information you obtain does not indicate EGHP coverage but Medicare was the secondary payer on a previous claim based on ESRD, verify the absence of EGHP coverage by inquiring of the beneficiary or the beneficiary's representative. If you verify the absence of EGHP coverage, annotate the bill to that effect (e.g., EGHP coverage lapsed, benefits exhausted). If the information you obtain indicates that EGHP coverage exists, obtain the information cited above from the beneficiary or the beneficiary's representative.

250.9 Billing .--

A. General.--If you determine, based on your development, that Medicare may be secondary to an employer plan, you must bill the EGHP for primary benefits.

B. Billing Medicare for Primary Benefits.--Bill Medicare for primary benefits only if the services were not rendered during a coordination period, or if the EGHP denies a claim because the beneficiary is not entitled to any benefits under the plan, or benefits under the plan are exhausted for the particular services, or the services are not covered by the EGHP.

If you believe that an EGHP may be primary payer, e.g., based on information in your records, ascertain whether primary EGHP benefits are payable, and if so, bill the EGHP for primary benefits. If an EGHP has denied your claim for primary benefits, annotate item 94 "Remarks" of the Medicare claim form with the reason for the denial of EGHP primary benefits and enter occurrence code 24 and date of denial in items 28 - 32. No attachment is needed. However, do not bill Medicare if the reason for the EGHP denial is that the EGHP offers only secondary coverage of services covered by Medicare. Medicare primary benefits may not be paid in this situation even if the EGHP has only collected premiums for secondary rather than primary coverage.

C. Billing Medicare for Secondary Benefits.—If an EGHP payment for Medicare covered services is less than your charges and the gross amount payable by Medicare (as defined in §250.10) in the absence of EGHP payment, and you do not accept and are not obligated to accept the plan payment as payment in full, secondary Medicare benefits may be payable on the claim in accordance with §250.10. Prepare the bill in accordance with §323C.

There may be instances where Medicare is secondary payer to more than one primary insurer, e.g., an individual covered under his own EGHP as well as under the EGHP of his spouse or under automobile insurance. In such cases, the other primary payers will customarily coordinate benefits. If a portion of the Medicare gross amount payable remains unpaid after the other insurers have paid primary payments, a secondary Medicare payment may be made.

D. Intermediary Recovery of Primary Benefits.—If primary Medicare benefits are paid to a RDF and the intermediary learns that an EGHP should have paid primary benefits for the items and services, the intermediary either recovers directly from the EGHP or from the RDF. When recovering from a RDF, the intermediary instructs you to file a claim with the EGHP for primary benefits, and upon receipt of the EGHP payment, to refund to Medicare the amount Medicare paid less the amount received from the EGHP. After the intermediary instructs you to file a claim for primary benefits with an EGHP, the intermediary follows up with you in 45 days to ascertain whether a claim has been filed and whether payment has been made by the EGHP. If you do not file a claim for primary benefits within 30 days after you have been instructed to do so, the intermediary recovers the Medicare primary payment from you, except where the reason you do not file a claim with the EGHP is because the beneficiary declines to sign the claims form. In that case, the intermediary recovers the overpayment directly from the EGHP.

Upon receipt of the EGHP refund, submit an adjustment bill showing the revised Medicare liability. When you receive an EGHP refund, credit amounts paid by the EGHP toward the deductible and coinsurance to the beneficiary's account or return to the beneficiary the amounts of the Medicare deductible and coinsurance already paid. You may retain any excess EGHP payment over the gross amount payable by Medicare. (See §250.11)

If duplicate payment was or will be made to you, i.e., you received or expect to receive both primary EGHP payments and primary Medicare benefits, the intermediary recovers from you the Medicare overpayment which is the difference between the Medicare primary payment and the amount Medicare should have paid as secondary payer. If Medicare paid you and the EGHP paid the beneficiary, the beneficiary is liable.

If the intermediary has not received an adjustment bill within 120 days of notifying you to file a claim with the EGHP, the intermediary follows up to determine the status of the claim. If the EGHP has denied the claim for a reason the intermediary would find acceptable had the intermediary requested payment from the EGHP directly, the recovery

action may be cancelled. If the EGHP has denied the claim for any other reason, or has not responded to your claim, the intermediary attempts to recover from the EGHP. Advise the intermediary immediately if you receive payment from the EGHP.

E. Recovery When a State Medicaid Agency Has Also Requested a Refund.--Where both Medicare and Medicaid have paid you benefits and you recover an amount from an EGHP, you are obligated to refund the Medicare payment up to the full amount of the EGHP payment before payment can be made to the State Medicaid agency. Only after Medicare has recovered the full amount of its claim do you have the right to reimburse Medicaid or any other entity.

250.10 Amount of Secondary Medicare Payments Where Employer Group Health Plan Pays In Part for Items and Services.

A. General.—If an EGHP payment for Medicare covered services is less than the RDF's charges for those services and less than the gross amount payable by Medicare (as defined below), and the RDF does not accept and is not obligated to accept the payment as payment in full, Medicare secondary payment can be made. The Medicare secondary payment will be the lower of:

- o the gross amount payable by Medicare minus the amount paid by the EGHP for Medicare covered services, or

- o the gross amount payable by Medicare minus any applicable Medicare deductible or coinsurance amount.

The gross amount payable by Medicare is the composite rate for maintenance dialysis services, or the composite rate plus the reasonable charge for separately billable items. (See §318.1.) The gross amount payable by Medicare is the amount Medicare would pay without regard to the effect of the Medicare deductible or coinsurance or the payment by the EGHP.

For detailed billing and reimbursement instructions, refer to §323.

B. Special Rules for Dialysis Equipment for Which Medicare Paid the Full Reasonable Cost.—Where a renal dialysis facility is paid its full reasonable costs for the purchase of dialysis equipment pursuant to an agreement with HCFA (see 42 CFR 405.690) bill the employer plan based on the usual rates in the area for the same or similar equipment. Any amounts received from the employer plan should be refunded to the intermediary or used to adjust future payment as the intermediary determines to be appropriate. There is no secondary Medicare payment in this situation because Medicare has already paid the facility 100 percent of its reasonable costs for the equipment. (The 100 percent reimbursement option for dialysis equipment is discontinued effective August 1, 1983. However, any equipment already purchased under a full reasonable cost reimbursement agreement will be handled under the pertinent regulations and terms of the agreement.)

250.11 Employer Group Health Plan Pays in Full.—If an employer plan payment for Medicare covered services equals or exceeds your charges or the gross amount payable by

Medicare for the services in the absence of employer plan coverage, or if you accept or are obligated to accept the plan payment as payment in full, no Medicare payment is due. Any excess of the employer plan payment over the gross amount payable by Medicare will not be subtracted from your Medicare reimbursement. When appropriate, submit a no payment bill in accordance with §323B.

250.13 Effect of EGHP Payment On Deductible and Coinsurance.-- EGHP payments are credited to the Part B deductible amounts. Thus, expenses that would be credited to a beneficiary's Part B cash or blood deductibles if Medicare were primary payer, are credited to the deductibles even if the expenses are reimbursed by an EGHP. This is true even if the EGHP paid the entire bill and there is no Medicare benefit payable. Also, EGHP payments to a facility are applied to satisfy a beneficiary's obligation to pay a Part B coinsurance amount. However, EGHP payments are credited to deductibles before being used to satisfy the coinsurance. (See §323.)

250.14 Limitation on Right of Facility to Charge a Beneficiary.--A renal dialysis facility may not charge a beneficiary or any other party, other than an insurer that is primary under §1862(b) of the Act, for Medicare covered services, if the facility has been or could be paid by an employer plan at least an amount equal to any applicable deductible or coinsurance amount. This limitation applies to situations where an insurer is primary under §1862(b) but offers only secondary benefits.

250.15 EGHP Erroneously Pays Primary Benefits.--If you determine that an EGHP has inappropriately paid primary benefits, bill Medicare as primary payer and refund to the EGHP the amount it paid, except for an amount equivalent to the Medicare deductible and coinsurance amounts, and charges for noncovered services.

250.16 Claimant's Right to Take Legal Action against an EGHP.--The Omnibus Budget Reconciliation Act of 1986 provides that any claimant has the right to take legal action against, and to collect double damages from, an EGHP that fails to pay primary benefits for services covered by the EGHP where required to do so under §1862(b) of the Act.

A200.—MEDICARE SECONDARY TO EMPLOYER GROUP HEALTH PLANS FOR INDIVIDUALS ENTITLED ON THE BASIS OF END STAGE RENAL DISEASE

A200.1. General.—Section 2146 of P.L. 97-35, the Omnibus Budget Reconciliation Act of 1981, effective October 1, 1981, provides for the coordination of benefits between Medicare and employer group health insurance plans during a 12-month period in the case of individuals entitled to Medicare solely on the basis of end-stage renal disease (ESRD). Under this provision Medicare is secondary payor if an employer group health plan covers the same services. This provision does not apply to beneficiaries entitled to Medicare benefits on the basis of being 65 years of age or because of disability.

For purposes of this instruction, an employer group health plan means a health plan that is of, or contributed to by, an employer, and that provides medical care directly or through other methods such as insurance or reimbursement to current or former empoyees, or to current or former employees and their families.

The amendment applies to services furnished on or after October 1, 1981 to entitled individuals whose 12-month periods began in October 1981 or later. Thus it can apply to services furnished as early as October 1981 where there is no waiting period for ESRD entitlement (transplant or self-dialysis training cases), but will not affect services rendered earlier than January 1982 in cases which Medicare entitlement follows a 3-month waiting period.

These manual provisions are an exception to the instructions contained in Sec. 219.3.

A200.2 Period in Which Medicare is Secondary to Employer Group Health Plans.—Medicare benefits are not payable or are subject to recovery to the extent that benefits have been paid, or will be paid promptly by an employer group health plan for services furnished during the 12-month period which begins with the earlier of (1) the month in which the individual starts a regular course of renal dialysis or (2) in the case of an individual who receives a kidney transplant, the first month in which the individual is eligible for Medicare benefits. Medicare is the secondary payor under these circumstances during the portion of this 12-month period in which the individual is entitled to Medicare. Since Medicare entitlement usually begins with the third month after the month in which the individual starts a regular course of dialysis, Medicare will usually be the secondary payor for the first 9 months of an individual's entitlement. However, for those individuals who undertake a course in self-dialysis training or who receive a kidney transplant during the 3-month waiting period, Medicare may be the secondary payor for up to the first 12 months of the individual's Medicare entitlement. Medicare may make supplementary payments if payment by the employer plan is less than the amount charged. Payments made by Medicare initially as a primary payor e.g., where the intermediary is not aware that the beneficiary has coverage under an employer group health plan or where prompt payment by the employer plan cannot be assumed, will be subject to recovery.

A200.3 Actions by Renal Dialysis Facilities Until Permanent Instructions are Issued.— Renal dialysis facilities submitting claims for services furnished on or after October 1, 1981 to ESRD beneficiaries whose Medicare entitlement began in October 1981 or later should immediately begin to annotate Medicare claim forms in the remarks item to show whether or not the individual has coverage under an employer group health plan. The name and address of the plan and the beneficiary's plan identification number should also be entered. Intermediaries will pay such claims for covered services and will maintain a list of the claims. When more detailed instructions are issued, these claims will be reexamined for possible recoupment of the Medicare reimbursement.

If the facility knows that payment has been made by an employer group health plan in such a case, it should enter "secondary payment" in the Remarks item on the claims form. The intermediary will make secondary payment, if appropriate, after it has received necessary instructions.

RENAL DIALYSIS FACILITY MANUAL
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300. HEALTH INSURANCE CARD AND OTHER EVIDENCE OF MEDICARE ENTITLEMENT

The Social Security Administration maintains the records of all persons entitled to health insurance. After entitlement is established, each beneficiary is issued a health insurance card (see Exhibit 1) by the central office of the Social Security Administration (or in some cases, by the Railroad Retirement Board). The card should be used in preparing claims for hospital and medical insurance. A health insurance card is acceptable without a signature. However, the patient should be asked to sign the card if he has not already done so.

Several other notices are prepared which are acceptable in lieu of the health insurance card. Persons who receive monthly social security payments and also have Medicare coverage receive either a Social Security Award Certificate (SSA-30) or Social Security Award Notice (SSA-30 BDI). These appear as exhibits 2 and 3. In most instances, newly entitled persons with ESRD that do not receive monthly social security payments first receive a letter signed by the Commissioner of Social Security giving Medicare entitlement information (see Exhibit 4). These persons also receive a Social Security Health Insurance Certificate, (SSA-31, see Exhibit 5) showing the health insurance claim number, date of entitlement, and type of coverage.

The health insurance claim number on these notices or the card is essential in locating the patient's record when a claim for benefit payment is made. Do not forward any billing form or bill supplement without the correct claim number; the claim cannot be processed if the number is missing or incorrect.

If the patient cannot furnish his health insurance card or other notice, as described above, he may have a utilization notice or explanation of benefits which shows his claim number. Such notices are sent to the beneficiary by the Department of Health and Human Services, the intermediary, or the carrier after payments are made under Part A or Part B. These notices, if current, may also indicate the patient's deductible status under Part B.

Ask each patient for his health insurance card (or other notice) to determine his health insurance entitlement status and obtain the correct health insurance claim number. If a patient has not yet applied for health insurance entitlement, advise him or someone on his behalf, to contact the nearest social security office. The facility may wish to arrange to bring such cases routinely to that office's attention. The social security office can also help a beneficiary replace a lost health insurance card.

304. IDENTIFYING HEALTH INSURANCE (HI) CLAIM NUMBERS

Most HI claim numbers are 9 digits with a letter, or letter and a numerical suffix, e.g., 000-00-0000A. They may also be 6 or 9-digit numbers with lettered prefixes, e.g., A-000-00-0000 or WD-000000. Numbers with one or more prefixes identify Railroad Retirement Board annuitants.

There are several possible suffixes. The most frequently used suffix for persons with ESRD not receiving cash benefits is T. For a person receiving cash benefits, the most frequently used suffix is A.

Suffixes with either a letter or number are shown below.

A*, B, B1 through B9, BA-BD, BG, BH, BJ, BK, BL, BN, BP, BQ, BR, BT, BW, BY

C1 through C9, CA through CK

D, D1 through D9, DA, DC, DD, DG, DH, DJ, DK, DL, DM, DN, DP, DQ, DR, DS, DT, DU, DW, DX, DY, D2

E, E1 through E9 EA, EB, EC, ED, EF, EG, EH, EJ, EK, EM

F1 through F8

J1 through J4

K1 through K9 KA, KB, KC, KD, ,KE, KF, KG, KH, KJ, KL, KM

M, M1

T

W, W1 through W9 WB, WC, WF, WG, WJ, WR, WT

*H may precede A, B, or C. The health insurance system does not use H since HA is equal to A, HB is equal to B, HC1 is equal to C1, etc.

304.1 Health Insurance Claim Numbers Assigned by the Railroad Retirement Board.-- The RRB began using the social security number in their numbering system during 1964. The numbers assigned prior to that item are 6-digit numbers; these were assigned in numerical sequence and have no special characteristics. However, both the 6-digit numbers and the 9-digit social security numbers, when used as claim numbers by the RRB, always have letter prefixes. (In rare cases, where a qualified railroad retirement beneficiary may have a claim number with less than 6-digits, add sufficient zeros between the prefix and other digits to make a 6-digit number, e.g., WD-001234.)

304.2 All-Inclusive List of Potentially Valid RRB Health Insurance Claim Numbers. --*

A-000000
A-000-00-0000

MA-000000, or
MA-000-00-0000

WA-000000, or
WA-000-00-0000

WD-000000, or
WD-000-00-0000

CA-000000, or
CA-000-00-0000

PA-000000, or
PA-000-00-0000

PD-000000, or
PD-000-00-0000

H-000000

MH-000000

WH-000000

WCH-000000

PH-000000

WCA-000000, or
WCA-000-00-0000 JA-000000

WCD-000000, or
WCD-000-00-0000

304.3 Change in HICN.—Changes in an individual's entitlement to social security or railroad retirement benefits may result in assignment of a different suffix or of a completely different HICN; e.g., an individual not entitled to monthly benefits (000-00-0000T) marries and becomes entitled to wife's benefits on her husband's account (111-11-1111B).

305. REDUCTION IN REIMBURSEMENT DUE TO P.L. 99-177, P.L. 100-119, and P.L. 100-203

A. General.--P.L. 99-177 requires a reduction in all Medicare program payments when the total Federal budget deficit exceeds set limits. P.L. 100-203 sets the reduction in program reimbursement at 2.324 percent for the period November 21, 1987 through March 31, 1988. You will be informed of the amount of the reduction for each Federal FY by your intermediary.

The intermediary reduces all Medicare program payments after applying deductible, coinsurance, and any applicable Medicare Secondary Payer (MSP) adjustments. It reduces each claim or interim payment (including PIP).

B. Definitions.--

Date of Service: The intermediary applies the reduction for all services for which the through date on the bill is on or after November 21, 1987 through March 31, 1988. You may bill earlier services separately to avoid the reduction.

Reduction Amount: Although the reduction amount for Medicare program payment is 2 percent for FY 1988, beginning November 21, 1987 a reduction of 2.324 percent was withheld for services on or after November 21, 1987 through March 31, 1988.

The amount of reduction is determined by October 15 for each year. For FYs after 1988, your intermediary will inform you of the specific percentage by which bills are reduced after the final determination of the amount is made. Intermediaries will hold any bills for services on or after October 1 until they receive the amount of reduction from HCFA.

C. Changes Required in Bill Payment Procedures.--You may bill separately for all services prior to November 21, 1987, in order to avoid the reduction of the entire bill. Split any bills spanning the Federal FY or November 31, 1987.

The intermediary reduces all bills with dates of service or through dates on or after November 21, 1987. It will split bills which may contain earlier services and will accept adjustment bills to correct earlier bills spanning November 21, 1987 or the beginning of a new Federal FY for services billed on a monthly basis.

You can expect reduction on final payments and interim payments (cost based interim payments). When payment is for laboratory services, the intermediary makes the reduction after it decides whether the charge or fee schedule is lower.

The intermediary adjusts payment amounts, not payment rates. It applies the reduction to the amount that would have been paid before P.L. 99-177, i.e., after reduction for deductible, coinsurance and MSP. This provides a slightly higher payment to you than applying the percentage reduction before deductible, coinsurance and MSP.

You may not collect the reduction amount from beneficiaries.

306. PART B DEDUCTIBLE

In each calendar year a cash deductible must be satisfied before payment can be made under supplementary medical insurance (SMI). The cash deductible is $75 effective January 1, 1982. Also effective January 1, 1982, only expenses incurred in the same calendar year can be used to satisfy the Part B deductible for services rendered in that year.

Bills count toward the deductible on the basis of incurred rather than paid expenses and are based upon the customary charge. Noncovered expenses do not count toward the deductible. Even though an individual is not eligible for the entire calendar year, i.e., his coverage begins after the first month of the year or he dies before the last month of the year, he is still subject to the full cash deductible.

308. PART B COINSURANCE

After the deductible has been satisfied, facilities are paid 80 percent of the reasonable charges. The patient is responsible for a coinsurance amount equal to 20 percent of the reasonable charges.

310. DETERMINING HOW MUCH TO CHARGE PATIENT BEFORE BILLING IS SUBMITTED FOR PART B REIMBURSEMENT

Ask the patient if he has any evidence that he has met the deductible, such as an explanation of Medicare benefits form. Consider any other available information on the patient's deductible status.

Where the deductible is met, collect 20 percent of the reasonable charges. Where the deductible is known to be met in part, collect no more than the unmet deductible and 20 percent of the remaining charge. When the deductible is not met or its status is unknown, collect no more than the cash deductible and 20 percent of the balance. Once the intermediary has been billed, do not collect or accept any additional money from the patient towards the deductible until the intermediary has supplied the amount of the deductible the patient must meet.

Beneficiary Request for Payment

312. FILING A REQUEST FOR PAYMENT

Medicare payment may not be made unless the beneficiary or his representative files a timely written request for payment and you submit a claim. To ensure that payment is neither curtailed nor denied, it is important that the beneficiary be made aware of the following circumstances.

- Payment may not be made unless the services are "reasonable and medically necessary."
- Incomplete or incorrect identifying information can delay the processing of a claim. Such claims may have to be returned by the intermediary for redevelopment.
- When neither the facility nor the beneficiary could know that the services were not covered, the waiver of liability provision may apply. (See §315.)

312.2 Request for Payment on Facility Record.—In place of signatures on billing forms, you may use a procedure under which the signature of the patient (or his representative under §314) on your records serves as the request for payment for your services, for physician services for which you are authorized to bill, and for any other physician services furnished in your facility. In the case of physician services, claims may be submitted on either an assigned or unassigned basis. ("Physician services" in this context means services by physicians which are not reimbursed as facility services which are submitted to the Part B carrier.)

To implement this procedure, incorporate language to the following effect in your records:

Statement to Permit Payment of Medicare Benefits
to Facility, Physicians and Patient

NAME OF BENEFICIARY HI CLAIM NUMBER

I request payment of authorized Medicare benefits to me or on my behalf for any services furnished me by or in (Name of facility), including physician services. I authorize any holder of medical and other information about me to release to Medicare and its agents any information needed to determine these benefits or benefits for related services.

The request is effective until revoked. If a patient objects to part of the request for payment, annotate the statement accordingly and notify any physician affected.

Under this procedure, indicate on the claim form that you have obtained the patient's signature by checking the block "Signature contained in the facility records", or, if the form does not contain such a block, by entering "Patient's request for payment in file" on the patient's signature line of the claim. A physician or medical group submitting claims under this procedure indicates that the facility has obtained the patient's signature by entering on the patient signature line of the claim, "Patient's request for payment on file in (name of facility)."

In using this procedure, the provider, physician or medical group undertakes:

- To complete and submit promptly the appropriate billing form for services to a Medicare beneficiary - even when assignment is not accepted for the physician services.

- To incorporate, by stamp or otherwise, information to the following effect on any bills sent to Medicare patients: "Do not use this bill for claiming Medicare benefits. A claim has been, or will be, submitted to Medicare on your behalf." This is necessary to prevent patients from submitting duplicate claims.

You also undertake to make the patient signature files available for carrier and intermediary inspection upon request.

The intermediary and carrier make periodic audits of signature files, selected on a random basis. The carrier may arrange with the intermediary for the latter to perform this function on its behalf.

312.3 Time Limitation for Filing Claims for Dialysis Services.—The beneficiary's request and your claim (HCFA-1450) must be filed on or before December 31 of the calendar year following the year in which services were furnished. Services furnished

in the last quarter of the year are considered furnished in the following year; i.e., the time limit is 2 years after the year in which such services were furnished. For example, a claim for services rendered September 30, 1979, must be filed by December 31, 1980. A claim for services rendered October 1, 1979, must be filed by December 31, 1981. Reimbursement cannot be made for claims filed after the time limitation except under the following conditions:

1. Where failure to file a timely claim was due to HCFA or intermediary error, the time will be extended through the last day of the sixth calendar month after the month in which the error is rectified.

2. The time limit is extended to the next workday if the last day for filing falls on a day which is not a Federal workday (i.e., Saturday, Sunday, legal holiday).

If error of the HCFA or its agents, or the patient, caused the bill to be filed late, attach a statement outlining the facts to the bill.

When the intermediary or HCFA determines that the late filing was the patient's fault, the patient is responsible for the bill; if the facility is at fault in not filing a timely bill, the facility can bill the patient only for the deductible and coinsurance amount.

314. EXECUTION OF THE REQUEST FOR PAYMENT

If at all practicable, the patient should sign the request at the time dialysis services begin.

In certain circumstances, this is impracticable; for example, when the individual is incompetent or otherwise is in such a condition that he should not be asked to transact any business. In this situation, his representative payee (i.e., a person designated by the Social Security Administration to receive monthly benefits on his behalf), a relative, legal guardian, or a representative of an institution (other than the facility) usually responsible for his care, or a representative of a governmental entity providing welfare assistance should, if present at time of start of services, be asked and permitted to sign on his behalf. A representative of the facility responsible for his care may be asked and permitted to sign on his behalf as a means of last resort.

315. SCOPE OF WAIVER OF LIABILITY PROVISION

The basic premise of the waiver provision in section 1879 of the Social Security Act is that beneficiaries and/or facilities who did not know and had no reason to know that services were not covered are protected from liability when the services were found, upon medical review, to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

If the beneficiary had knowledge or should have had knowledge of the noncoverage of services, the ultimate liability rests with the beneficiary. When neither the beneficiary nor the facility knew or reasonably could have been expected to know that the services were not covered, Medicare accepts liability. Where the facility had or should have had such knowledge, liability falls upon the facility; i.e., the facility can not charge the beneficiary for such services other than the Part B deductible and coinsurance, even

though program payment is not made. (The Part B deductible and coinsurance may be charged to the beneficiary even where he receives the benefit of this waiver provision.) Contact intermediaries for a more detailed discussion of this provision.

317. FORM HCFA-1483, PROVIDER BILLING FOR MEDICAL AND OTHER HEALTH SERVICES

All independent renal dialysis facilities use, as a request for payment, the HCFA-1483, Provider Billing for Medical and Other Services. Submit the HCFA-1483 for maintenance dialysis patients to the intermediary monthly, in all cases where dialysis services were rendered, whether the deductible has or has not been satisfied. However, do not submit an HCFA-1483 if (1) the patient is not enrolled under Part B, or (2) workers' compensation or (3) other governmental agencies will pay the bill.

The HCFA-1483 is available in the following form sets. (The use of a form set is subject to intermediary approval.)

1. HCFA-1483—snap-out, three-part (billing copies only);
2. HCFA-1483 (EB)—snap-out, four-part (three billing copies, one copy of beneficiary notice);
3. HCFA-1483 (C)—pin feed, three-part (billing copies only); and
4. HCFA-1483 (c) (EB)—pin feed, four-part (three billing copies, one copy of beneficiary notice).

317.1 General Information Concerning the Composite Rate.—All infacility dialysis treatments and all home dialysis treatments billed under Method I (see §318.1) are billed and reimbursed under the composite rate reimbursement system.

All items and services included under the composite rate must be furnished by the facility, either directly or under arrangements, to all of its dialysis patients who elect this method of reimbursement. If it fails to furnish (either directly or under arrangements) any part of the items and services covered under the rate, then the facility cannot be paid any amount for the part of the items and services that the facility does furnish. These items and services include:

1. medically necessary dialysis equipment and dialysis support equiment;
2. home dialysis support services including the delivery, installation, maintenance, repair, and testing of home dialysis equipment, and home support equipment;
3. purchase and delivery of all necessary dialysis supplies;
4. routine ESRD related laboratory tests; and
5. all dialysis services furnished by the facility's staff.

Some examples (but not an all-inclusive list) of items and services that are included in the composite rate and may not be billed separately when furnished by a dialysis facility are:

1. staff time used to administer blood;
2. declotting of shunts and any supplies used to declot shunts;
3. oxygen and the administration of oxygen; and
4. staff time used to administer nonroutine parenteral items.

See Chapter 27 of the Provider Reimbursement Manual, Part I, for instructions on reimbursement of ESRD services.

318. BENEFICIARY SELECTION FORM HCFA-382, FOR HOME DIALYSIS PATIENTS

A. General Information.—Medicare beneficiaries dialyzing at home can choose between two separate methods on how they wish to have the Medicare program pay for home dialysis care (exclusive of physician services). Have all current home dialysis patients choose one of the two methods, sign the Beneficiary Selection Form, HCFA-382, and return it to your intermediary. Future home dialysis patients sign the form after making their selection as soon as they go on home dialysis.

Effective with the date that the beneficiary makes the initial selection, reimbursement is handled in this manner until December 31, 1984. A beneficiary may change the selection by submitting a new beneficiary selection form. All changes received in a 1-year period will be effective the following January 1 and remain in effect for the entire calendar year.

B. Home Dialysis Billing Options

Method I

If the dialysis facility with which the Medicare home patient is associated assumes responsibility for providing all home dialysis equipment and supplies, the beneficiary may decide to have the facility provide these items. For this service, the facility would receive the same Medicare dialysis payment rate as it would receive for an infacility patient under the composite rate system. Under these arrangements, the beneficiary is responsible for paying any unmet Part B deductible and the 20-percent coinsurance on the Medicare rate to the facility.

Method II

The beneficiary retains the right to deal directly with the Medicare program and make arrangements for securing the necessary supplies and equipment to dialyze at home. Under this arrangement, the beneficiary is responsible for dealing with the facility or the various suppliers and the Medicare program to arrange for payment. The beneficiary is also responsible to the facility or suppliers for any unmet Part B deductible and the 20-percent Medicare coinsurance requirements. The dialysis facility may not bill for or receive the composite rate for treatments furnished to a patient who chooses this option.

The facility must furnish and bill for all home dialysis support services. Only the facility may be paid for home dialysis support services; the beneficiary may not be paid these benefits. However, the beneficiary may obtain the remaining supplies and equipment from the facility that are not obtained from a supplier. If the beneficiary chooses the facility to act as a supplier, the facility may bill the intermediary for any supplies and/or equipment it provides. Independent facilities are reimbursed on a reasonable charge basis for any home dialysis support services they furnish; and on a reasonable cost basis for any supplies or equipment it furnishes.

318.1 Completion of Items on Form HCFA-1483, Under the Composite Rate

ITEM	PROCEDURE
1	Patient Identification - Enter the patient's last name, first name, and middle initial from his health insurance card or other acceptable notice. (See §300.)
2	Health Insurance Claim Number -Enter the patient's claim number as shown on his health insurance card, other evidence of entitlement, or as reported by the social security office.
3	Patient's Address - Show the patient's mailing address. If the patient is an inpatient of another institution, also show "inpatient of (Name of Institution)" and address of the institution.

4 and 5

Date of Birth and Sex-Enter the patient's date of birth and sex. If only the year of birth is available, enter that. The date of birth and the sex of the patient are personal characteristics used to verify the identity of the patient as a Medicare beneficiary.

6, 7, and 8

Facility Identification-Enter the facility's name and address, the ZIP code, and the identification number assigned by the Health Care Financing Administration. These items can be preprinted on all copies of the forms, if desired. Enter the patient's medical record number only if you assign one for your own purposes.

9

Type of Service-Check box "C" "other" which indicates that the patient is a "nonpatient." No more than one block may be checked. Enter a code and explanation to identify the type of dialysis involved. The codes and explanations are:

1 - Hemodialysis
2 - Peritoneal, CCPD; and
3 - CAPD

10 and 11

Complementary Coverage Information-If the patient desires that information about the claim be sent to a complementary insurer or welfare agency and you do not object, show the name and address of the organization or agency in item 10, and the policy or identification number in item 11.

12

Patient's Certification-Have the patient or his authorized representative read and sign the statement on the form or similar statement incorporated in your records. (See §312.2.)

If the signature is obtained on form HCFA-1483, it is sufficient if it is legible on the original only. If you obtain the signature on your own form, check the block marked "Contained in Provider's Record."

If the patient cannot sign his name because of his physical or mental condition, another person may sign on his behalf e.g., John J. Jones by Jack A. Smith.

Briefly explain why the patient did not sign the form and show the relationship of the signer to the

patient. Retain this explanation in the file if the signature is obtained on your own record. If a signature other than the patient's is on form HCFA-1483, an explanation must accompany or be included on the billing form.

Read the statement to a patient who cannot read. A signature by mark must be witnessed by a person who knows the patient. Enter the name and address of any person witnessing a signature by mark.

13 Nature of Illness or Injury.—List here, from the patient's medical record, the nature of the illness or injury for which dialysis services were given. Use acceptable medical terminology, such as is contained in International Classification of Diseases Adapted, Current Medical Terminology, etc. If the bill includes charges for the rental or purchase of durable medical equipment used in home dialysis, enter the reason the equipment is required and the physician's estimated duration of need (in months). For many patients the duration will be "indefinite." (See §213.2 for more details about the period of medical necessity for home dialysis equipment. Also, see §212 for the coverage of home dialysis equipment.)

14 Surgical Procedures.—Not applicable.

15 Statement of Services.—The HCFA-1483 has various types of services preprinted on lines A through H. Include on line 151 other services not specifically listed.

Under the composite rate sytem, do not complete items 15L, 15N, 18, and 19.

15C Laboratory.—The following list identifies laboratory tests and their frequencies included in the composite rate. Do not bill separately for laboratory tests included in the composite rate. Include these charges in 15K. All tests whose costs were included in establishing the composite rate must be performed by you and reimbursed only under the composite rate or be performed by an outside laboratory, billed to you and reimbursed only under the composite rate.

Laboratory Tests For Hemodialysis, Peritoneal Dialysis, and CCPD Included in the Composite Rate

1. Per Treatment
   All hematocrit and clotting time tests furnished incident to dialysis treatments.

2. Weekly
   Prothrombin time for patients on anti-coagulant therapy
   Serum Creatinine
   BUN

3. Monthly

Serum Calcium	Serum Bicarbonate	Alkaline Phosphatase
Serum Chloride	Serum Phosphorous	SGOT
Total Protein	Serum Potassium	LDH
CBC	Serum Albumin	

Laboratory Tests For CAPD Included in the Composite Rate

Monthly		
BUN	Magnesium	Alkaline Phosphatase
Creatinine	Phosphate	LDH
Sodium	Potassium	SGOT
CO2	Total Protein	HCT
Calcium	Albumin	Hgb
		Dialysate Protein

Independent facilities may not bill for separately billable laboratory tests. The independent laboratory that provided the service must do the billing. Fees will be established at 60 percent of the prevailing charge and the bills go to the carrier.

Independent facilities may not bill separately for collecting a specimen for testing. This is already included in the composite rate.

15E

Enter the charges for nonroutine parenteral items in this item.

Parenteral items routinely used in the dialysis procedure are covered under the facility's composite rate. Following is a list of the routine items that may not be billed separately:

heparin	saline
protamine	glucose
mannitol	dextrose
antiarrythmics	

Also, included in routine pharmacy would be topical anesthetics (e.g., xylocaine).

There are other parenteral items that are not routinely furnished as a part of the dialysis procedure but that may be medically necessary for some patients receiving dialysis. When furnished to infacility dialysis patients these may be billed separately provided they are justified for medical necessity. They include:

antibiotic	analgesics
hematinics	sedatives
anabolics	tranquilizers
muscle relaxants	

These other parenteral items (i.e., those not included as routine) may only be billed by you if they are actually administered in your facility by your staff.

15F

Where blood is furnished on an outpatient basis, show the charges for unreplaced blood on line F. This includes only the charge to the facility for the blood itself. Bill processing fees charged by the blood supplier in item 15I.

Staff time used to administer blood are included in the composite rate and may not be billed separately.

Supplies used to administer blood may be billed separately in item 15I.

15I

Enter the charges for other services not specifically listed in items 15A thru 15H, on line 15I.

15J

Total-Enter the total charges of items listed in 15I.

The items shown below are coded in the blank space below item 15I. Enter the appropriate letter (K, L, M, N).

15K

Dialysis treatments are billed in this item. Show the number of treatments in the space to the left of the covered charges column. Show the charge per dialysis treatment. Include the charges for laboratory tests included in the composite rate calculation as part of your dialysis charge.

Facilities are reimbursed the composite rate or the composite rate adjusted (composite rate reduced by $12.00) per treatment for those beneficiaries using dialysis machines purchased under the 100-percent program. (See code "5" in REMARKS.)

1. Extended Peritoneal - Peritoneal dialysis is usually done in sessions of 10-12 hours duration, 3 times per week, and in this case each session would be billed and reimbursed as one treatment.

   However, some peritoneal dialysis is done only once or twice a week for a longer duration per treatment. Therefore, peritoneal dialysis sessions of between 20-29 hours duration will be billed and reimbursed as 1 1/2 treatments.

   Extended peritoneal dialysis sessions of 30 hours or more, given once a week, in place of 2 or 3 sessions of shorter duration will be billed and reimbursed as three treatments.

2. CCPD and CAPD Sessions - CCPD and CAPD is billed and reimbursed on the basis of an equivalence rate. Because CCPD and CAPD are continuous therapies, and not furnished in discrete treatments, they are reimbursed at three times the facility's per treatment composite rate per week. Show the number of patient weeks (including any fraction of a patient week) in place of the number of treatments. If the patient is hospitalized, is dialyzed in a facility, or the facility bills on a monthly basis and there are 31 days in the month, the odd days are accounted for by prorating the weekly rate by 1/7 for each day.

   Example

   Facility A has a CAPD patient who dialyzes on CAPD for the full month of January. Facility A bills on a monthly basis and its per treatment composite rate is $130.

   For the 3 additional days:
   CAPD daily rate = 1/7 x $390 = $55.71
   3 x $55.71 = $167.13

   The proper total amount billed for January is:

   $1, 560 + $167.13 = $1727.13

   Part B
   Assume the patient's deductible amount is met.
   The intermediary payment is 80% x $1,727.13 = $1381.70.

Your intermediary may require that you bill only full weeks (e.g., every 4 weeks) to avoid the above computation.

3. Training Sessions

Hemodialysis, Peritoneal Dialysis, and CCPD

Bill training sessions for these types of dialysis at their approved frequencies. You will be reimbursed the composite rate plus $20.00.

CAPD Training Sessions

CAPD training sessions are reimbursed the composite rate plus $12.00.

A maximum of 15 CAPD training sessions are covered routinely for each patient. Enumerate the training session(s) on the bill; e.g., "CAPD training sessions nos. 6-10." Claims for additional training sessions beyond 15 must be documented for medical necessity.

4. Infacility Back-up Dialysis

A back-up dialysis is an infacility dialysis furnished to a home dialysis patient.

Complete a separate bill when back-up dialysis is furnished to a home patient.

If it is necessary to supplement the patient's CAPD during training with either hemodialysis or peritoneal dialysis sessions, bill these sessions as any other session you furnished.

Indicate on the bill the number of the session and that this session is supplemental to CAPD training; e.g., "CAPD training supplemental dialysis session no. 2." Normally, not more than three supplemental dialysis sessions during the training course are necessary.

Back-up dialysis is always completed in item 15K and a setting code "6" must appear in the "Remarks" section of the HCFA-1483 (see "Remarks").

15M Equipment and Equipment Related Services Provided to Home Dialysis Patients

A. Home Dialysis Equipment - This may not be billed separately and is included in the composite rate.

B. Delivery, Installation, Repair, Maintenance, and Removal Services - These services may only be billed separately under a 100-percent reimbursement agreement for home dialysis equipment. The composite rate adjusted is used to reimburse the remaining items and services covered under the composite rate. (See item 15K.) Enter a code "15" in the Remarks section of the HCFA-1483.

16 Statement Covers Period

A. Regardless of the normal billing cycle, do not include charges for dialysis equipment, supplies and/or services rendered prior to August 1, 1983 with those items included in the composite rate. Separate billings are required.

B. Show the dates during which the patient's care was under the supervision of the facility. Exclude dates when the patient's care was under the supervision of another entity (e.g., hospital, another ESRD facility, SNF) from the statement covers period.

17 Blood Information

Complete item 17A if charges are shown in item 15F.

18, 19, 20, 21 Not Applicable

22 Signature of Facility Representative - Before forwarding the billing to the intermediary, a facility representative must sign here. A stamped signature is acceptable.

23, 24, 25 Not Applicable

Remarks

Enter the appropriate code and explanation to denote the type of dialysis setting involved as follows:

1. Full Care in Unit;
2. Self-Care in Unit;
3. Self-Care Training;
4. Home;
5. Home, 100-Percent Program;
6. Infacility Back-Up Dialysis.

Enter only one related setting code per bill. If more than one setting is involved, submit separate bills.

Enter the annotation "Medicare Primary Payer" where Medicare is the primary payer.

Enter the special annotation where Medicare is not the primary payor because an employer group health plan is primary to Medicare for ESRD beneficiaries. See §323 for required annotations.

318.2 Special Instructions On Completion of the HCFA-1483 For Home Dialysis Items and Services Billed Under Direct Dealing (Method II).—These instructions apply only to home dialysis items and services billed and reimbursed under Method II. With Method II, all home dialysis items and services must be billed and reimbursed on an itemized basis.

Under Method II, the home dialysis patient may choose to obtain home dialysis equipment and/or supplies directly from a supplier that is not a facility. In this case the patient (or supplier) bills the Medicare carrier. However, if the home dialysis patient chooses to obtain home dialysis equipment and/or supplies from the facility, the facility bills its intermediary on an itemized basis using a HCFA-1483.

There is no choice with respect to home dialysis support services. Only a dialysis facility may furnish, bill for, and be reimbursed for these services. Bill your intermediary for all home dialysis support services on an itemized basis using a HCFA-1483.

Complete all items on the HCFA-1483 in accordance with the instructions in §318.1 except for the following:

Item	Procedure
15C	Laboratory.—Do not bill for laboratory tests. The independent laboratory that provided the service must do the billing. Fees have been established at 60 percent of the prevailing charge and the bills go to the carrier. A specimen collection fee of up to $3.00 is allowed only for: (1) drawing a blood sample through venipuncture (e.g., inserting into a vein a needle with a syringe or vacutainer to draw the specimen), or (2) collecting a urine sample by catheterization. A specimen collection fee is not allowed for blood samples drawn from a capillary. You must draw the sample in order to bill for it. If so, bill your intermediary. Only one collection fee is allowed for each specimen and for each patient encounter.

15E

Pharmacy.—Enter the cost of all routine ESRD parenteral items in this item. Routine parenteral items (see §318.1 item 15E) may be billed without documentation for medical necessity and may be billed by you regardless of where they are furnished. All other parenteral items may only be billed by you if they are administered in your facility by your staff. They must be documented for medical necessity. The administration of parenteral items (both staff time and supplies) are covered and billed in line item 15I.

15I

Other.—Enter the charges for other services, not specifically listed in items 15A thru 15H, on line 15I.

The items shown below are coded in the blank space below item 15I. Enter the appropriate letter (K, L, M, N).

15K

Sessions - Normally do not complete this item under Method II. However, back-up dialysis furnished to home patients in the facility may be billed and reimbursed on a separate bill. (See §318.1 item 15K.)

15L

Supplies - Facilities furnishing home dialysis supplies to patients choosing to deal directly (Method II) enter their cost for covered supplies furnished by or through the facility.

Supplies distributed directly to a home patient by a manufacturer, but billed to the facility, are considered to be furnished through the facility on the date the supplies are delivered to the patient.

Home Dialysis Kits - If items are ordered as a kit through the facility, the kit identification is included as a line item on the HCFA-1483.

Two Month's Quantity - Do not bill for supplies in excess of 2 month's anticipated usage.

15M

A. Equipment

Facilities furnishing home dialysis to their home patients enter their cost for covered equipment furnished by, or through, the facility on this line.

Home dialysis equipment furnished by independent dialysis facilities is reimbursed on a reasonable cost basis. Therefore, equipment that is owned by a facility may not be furnished by the facility on a rental basis. It must be sold. It is billed and reimbursed on either a lump-sum or periodic purchase payment basis.

A facility may only furnish home dialysis equipment on a rental basis if the facility itself rents the equipment from a supplier or manufacturer.

Equipment distributed directly to a home patient by a manufacturer, but billed to the facility, is considered to be furnished through the facility on the date the equipment is delivered to the patient.

B. Delivery, Installation, Repair, and Maintenance of home dialysis equipment.—Bill these services as separate line items.

Services furnished with respect to dialysis equipment purchased before August 1, 1983, under the 100-percent reimbursement agreement continue to be reimbursed at 100 percent of their cost as per the agreement.

15N

A. Home Dialysis Support Services - Enter the cost of all home support services. All home dialysis support services must be furnished by a renal dialysis facility and only a facility may bill for them.

B. Support Services Furnished to Home CAPD Patients - The sponsoring CAPD certified facility enters the cost of support services it furnishes to home CAPD patients. These include but are not limited to: (1) changing the connecting tube (also referred to as an "administration set"), (2) watching the patient perform CAPD and assuring that it is done correctly, and reviewing for the patient any aspects of the technique he may have forgotten, or informing the patient of modifications in apparatus or technique, (3) documenting whether the patient has or has had peritonitis that requires physician intervention or hospitalization, (4) inspection of the catheter site. These services must be furnished in accordance with a written plan of treatment required for home dialysis patients. Each of the CAPD support services may be billed routinely at a frequency of once per month. Any support services furnished in excess of this frequency must be documented for medical necessity. For example, the patient may contract peritonitis and require an unscheduled visit.

C. Setting - Home dialysis support services may be furnished either in the patient's home or in the facility. In either case, enter setting code "4" home dialysis. Note, a back-up dialysis is not a home support service.

16 Statement Covers Period - Enter the date of the first and last service furnished during the billing period.

A. Home Dialysis Supplies - If the only item billed is for home dialysis supplies, enter the date of delivery as both the First Service and Last Service dates.

B. Home Dialysis Equipment - If the only item billed is for rented home dialysis equipment, enter the date of delivery as both the First Service and Last Service dates. On subsequent monthly bills prepared for subsequent payments, show the same day of the month as that shown on the initial bill. For example, if the equipment was delivered on September 8, 1979, the first HCFA-1483 shows 9/8/79 as the date of both the First and Last Service. The next bill shows 10/8/79, 11/8/79, 12/8/79, etc. A facility may only furnish home dialysis equipment on a rental basis if the facility itself rents the equipment.

If the only item billed is home dialysis equipment sold to the patient in one lump sum, enter the date of delivery as both the First Service and Last Service dates. Only one bill is submitted even though reimbursement for expensive items may be made in several installments.

C. Home Dialysis Support Services - If the only item billed is for support services furnished on a single day enter that date as both the First Service and Last Service dates.

17 Blood Information - Complete this item if charges are shown in item 15F.

UNIFORM BILLING

320. COMPLETION OF FORM HCFA-1450 BY INDEPENDENT FACILITIES FOR HOME DIALYSIS ITEMS AND SERVICES BILLED UNDER THE COMPOSITE RATE (METHOD I) — (SEE §§317.1ff. FOR DETAILS ON THE COMPOSITE RATE REIMBURSEMENT SYSTEM).

The HCFA-1450 (also known as the UB-82) is a uniform institutional provider bill suitable for use in billing multiple third party payers. Where HCFA determines that the form is to be used for Medicare, it is used in lieu of the HCFA-1483. The HCFA-1450 contains all data elements contained on the HCFA-1483. In addition, a number of data elements not required by Medicare, but required by other payers, are included. For Medicare billing, complete only the information required by Medicare. When billing multiple third parties complete all items required by each payer, and forward a copy to each payer.

Item 1. (Untitled) - Provider Name, Address, and Telephone Number
Required. The minimum entry is your name, city, State, and zip code. The post office box number or street name and number may be included. The State should be abbreviated using standard post office abbreviations. Five or nine digit zip codes are acceptable.

Item 2. (Untitled)
Not Required. This is one of the fields which have not been assigned for national use. Use of the field, if any, is assigned by the State Uniform Bill Committee and is uniform within a State.

Item 3. Patient Control Number
Not Required. Some providers use an identifying number to facilitate retrieval of case records and posting payment. Where you have made arrangements to use this number in communications with your intermediary, show the number.

Item 4. Type of Bill
Required. This three-digit numeric code gives three specific pieces of information. The first digit identifies the type of facility. The second classifies the type of care. The third indicates the sequence of this bill in this particular episode of care. It is referred to as a "frequency" code.

Code Structure (only codes used to bill Medicare are shown).

First Digit - Type of Facility
Enter code "7" Clinic.

Second Digit - Classification
Enter code "2" Free-Standing Renal Dialysis Center.

Third Digit - Frequency

1 - Admit Through Discharge Claim	Use this code for a bill encompassing an entire inpatient confinement or course of outpatient treatment for which you expect reimbursement from the payer.

5 - Late Charge Only	Use this code only for outpatient claims.
7 - Replacement of Prior Claim	Use this code to correct (other than late charges) a previously submitted bill. This is the code applied to the corrected or "new bill.
8 - Void/Cancel of a Prior Claim	Use this code to indicate that this bill is an exact duplicate of an incorrect bill previously submitted. Submit a code "7" (Replacement of Prior Claim) to show the corrected information.

Item 5. Blue Cross/Blue Shield Provider Number
Not required.

Item 6. Federal Tax Number
Not required.

Item 7. Medicare Provider Number
Required. This is the six-digit number assigned by Medicare.

Item 8. Medicaid Provider Number
Not required.

Item 9. Untitled
See item 2, above.

Item 10. Patient's Name
Required. Enter the patient's name with the surname first, then first name, and middle initial, if any.

Item 11. Patient's Address
Required. Enter the patient's full mailing address including street number and name, post office box or RFD, city, State, and Zip code.

Item 12. Patient's Birthdate
Required. Enter the month, day, and year of birth numerically as MM-DD-YY. If the date of birth could not be obtained after reasonable effort, zero fill the field.

Item 13. Patient's Sex
Required. An "M" for male or an "F" for female.

Item 14. Patient's Marital Status
Not required.

Item 15. Admission Date
Not required.

Item 16. Admission Hour
Not required.

Item 17. Type of Admission
Not required.

Item 18. Source of Admission
Not required.

Item 19. Accident Hour
Not required.

Item 20. Discharge Hour
Not required.

Item 21. Patient Status
Not Required.

Item 22. Statement Covers Period (From - Through)
Required. Show the dates during which the patient's care was under the supervision of your facility. Exclude dates when the patient's care was under the supervision of another entity (e.g., hospital, another ESRD facility, SNF) from the statement covers period.

Item 23. Covered Days
Not required.

Item 24. Noncovered Days
Not required.

Item 25. Coinsurance Days
Not required.

Item 26. Lifetime Reserve Days
Not required.

Item 27. (Untitled)
See item 2, above.

Use of Occurrence and
Occurrence Span Fields (Items 28-33, Below)

Due to the varied nature of occurrence and occurrence span codes, provisions have been made to allow the use of both type codes within each. The occurrence span code can contain an occurrence code where the "Through" date would not contain an entry. This allows the use of as many as six occurrence codes.

When item 33 is utilized, items 31 and 32 may be utilized to contain the "From" and the "Through" dates of an occurrence span code. In this case, the code in item 31 is the occurrence span code and the occurrence span "From" date is in the date field. Item 32 contains the same occurrence span code as the code in item 31 and the occurrence span "Through" date is in the date field.

This necessitates that the occurrence and occurrence span codes be mutually exclusive. Occurrence codes have values from 01 through 69 and occurrence span codes have values from 70 through 99.

Items 28, 29, 30, 31, and 32. Occurrence Codes and Dates
Required. Enter code(s) and associated date(s) defining specific event(s) relating to this billing period. Event codes are two numeric digits. Show dates as six numeric digits (MM-DD-YY). When occurrence codes 01-04 and 24 apply they must be accompanied by the appropriate value code in items 46-49 if there is another payer involved.

Code Structure (only codes used to bill Medicare are shown).

Code	Title	Definition
01	Auto Accident	Enter the date of an auto accident. Use this code to report an auto accident that involves liability insurance.
02	Auto Accident/No Fault Insurance Involved	Enter the date of an accident where the State has applicable no-fault liability laws (i.e., legal basis for settlement without admission of proof of guilt). Use this code to report the date of an accident that involves auto medical/no-fault insurance.
03	Accident/Tort Liability	Enter the date of an accident resulting from a third party's action that may involve a civil court process in an attempt to require payment by the third party, other than no-fault liability. Use this code to report a non-automobile accident. Auto accidents are covered by codes 01 and 02.
04	Accident/Employment Related	Enter the date of an accident which relates to the patient's employment. (See §223.)

05	Other Accident	Enter the date of an accident not described by the above codes. Use this code to report that you have developed for other casualty related payers and have determined that there are none.
24	Date Insurance Denied	Enter the date you received the denial of coverage from a higher priority payer.
33	First Month of the 12 Month Coordination Period for ESRD Beneficiaries Covered by EGHP	Code indicates the first day of the first month of the 12 month period during which Medicare benefits are secondary to benefits payable under an EGHP.

Item 33. Occurrence Span Code and Dates
Not required.

Item 34. (Untitled except on Patient Copy of the bill.) Responsible Party Name and Address
Required. Space is provided to use a window envelope if you use the patient copy of the bill set. For claims which involve payers of higher priority than Medicare as defined in item 65, enter the address of the other payer in this item or item 94 (remarks).

Items 35, 36, 37, 38, and 39. Condition Codes
Required. - Enter the corresponding code to describe any of the following conditions that apply to this billing period. Note that one of the codes 71-76 will be applicable for every bill.

Code structure (Only codes effecting Medicare payment/processing are shown).

CODE	TITLE	DEFINITION
02	Condition is Employment Related	Enter this code if the patient alleges that the medical condition causing this episode of care is due to environment/events resulting from employment.
04	Patient is HMO Enrollee	Enter this code to indicate the patient is a member of a HMO.
71	Full Care in Unit	Enter this code to indicate the billing is for a patient who received staff-assisted dialysis services.

72	Self-Care in Unit	Enter this code to indicate the billing is for a patient who managed his own dialysis services without staff assistance.
73	Self-Care in Training	Enter this code to indicate the billing is for special dialysis services where a patient and his helper (if necessary) were learning to perform dialysis.
74	Home	Enter this code to indicate the billing is for a patient who received dialysis services at home but code 75 below did not apply.
75	Home 100 Percent Reimbursement	Enter this code to indicate the billing is for a patient who received dialysis services at home, using a dialysis machine purchased under the 100 percent program.
76	Back-up Infacility Dialysis	Enter this code to indicate the billing is for a home dialysis patient who received back-up dialysis in your facility.

Item 40. Pints of Blood Furnished
Required. Enter the total number of pints of blood or units of packed red cells furnished, whether or not replaced. Report blood only in terms of complete pints rounded upwards, e.g., show 1 1/4 pints as 2 pints. This entry serves a basis for counting pints toward the blood deductible.

Item 41. Pints of Blood Replaced
Required. Enter the total number of pints of blood donated on the patient's behalf. Where one pint is donated, one pint is replaced. If arrangements have been made for replacement, show pints as replaced. If you charge only for the blood processing and administration, i.e., you do not charge a "replacement deposit fee" for unreplaced pints, the blood is considered replaced for purposes of this item. In such cases, show all blood charges under the 39X revenue code series (blood administration).

Item 42. Pints of Blood Not Replaced
Required. Enter the difference between the number of pints of blood furnished and the number of pints replaced.

Item 43. Blood Deductible Pints
Required. Enter the number of unreplaced deductible pints of blood supplied. If all deductible pints furnished have been replaced, make no entry.

Item 44. Special Program Indicator
Not Required.

Item 45. (Untitled)
See item 2, above.

Items 46, 47, 48, and 49. Value Codes and Amounts Required. Enter a code(s) and related dollar amount(s) to identify data of a monetary nature necessary for the processing of this claim. The codes are two numeric digits, and each value allows up to eight numeric digits (000000.00). Never show negative amounts. If more than one value code is shown for a billing period, codes are shown in ascending numeric sequence. There are two lines of data, line "a" and line "b." Use items 46a through 49a before items 46b through 49b (i.e., use up the first line before using the second).

Code Structure (Only codes used to bill Medicare are shown.)

Code	Title	Definition
06	Medicare Blood Deductible	Part B Code indicates the amount that the patient paid for unreplaced deductible blood.
07	Medicare Cash Deductible	Part B Enter this code to indicate that the amount shown is the Part B cash deductible the patient paid in cases where the Part B blood deductible was also paid. In all other cases, the entry in item 60 reflects the part B deductible paid by this patient and no entry is needed in this item.
13	ESRD Beneficiary in the 12-Month Coordination Period With An EGHP	Enter this code to indicate that the amount shown is that portion of a higher priority EGHP payment made on behalf of an ESRD beneficiary that you are applying to covered Medicare charges on this bill. If you enter six zeros (0000.00) in the amount field, you are claiming a conditional payment. (See §250.)
14	Automobile, No-Fault, or Any Liability Insurance	Enter this code to indicate the amount shown is that portion of a higher priority automobile, no-fault, or liability insurance payment made on behalf of a Medicare beneficiary that you are applying to covered Medicare charges on this bill. If you enter six zeros (0000.00) in the amount field, you are claiming a conditional payment because the other insurer has denied coverage or there has been a substantial delay in its payment.

Code	Title	Definition
15	Workers' Compensation Black Lung	Enter this code to indicate the amount shown is that portion of a higher priority WC insurance payment made on behalf of a Medicare beneficiary that you are applying to covered Medicare charges on this bill. If you enter six zeros (0000.00) in the amount field you are claiming a conditional payment because there has been a substantial delay in the other payer's payment. (See §223.)
16	VA, PHS, Other Federal Agency	Enter this code to indicate the amount shown is that portion of a higher priority VA, PHS, or other Federal Agency's payment made on behalf of a Medicare beneficiary that you are applying to covered Medicare charges on this bill. (See §220.)

Item 50. Revenue Description

Required. Enter a narrative description or standard abbreviation for each revenue code shown in column 51 on the adjacent line in column 50. The information assists clerical bill review. "Other" code categories descriptions are locally defined and individually described on each bill. Refer to §318.1 items 15C through 15N for detailed information on when to bill for these revenue centers.

Unlabeled Column Required with Peritoneal Dialysis

When a revenue code in the 83x series (peritoneal dialysis) is placed in item 51 an entry must also appear in the untitled column to the left of item 51. This entry identifies the duration (number of hours) of the peritoneal treatments.

Peritoneal dialysis is usually done in sessions of 10-12 hours durations 3 times per week, and in this case each session is billed and reimbursed as one treatment. Enter the number of hours for each session in this column. Enter the number of sessions (treatments) in item 52.

Some peritoneal dialysis is done only once or twice a week for a longer duration per treatment. Therefore, peritoneal dialysis sessions of between 20-29 hours duration will be reimbursed as 1 1/2 treatment. However, for purposes of billing, since fractions or decimals are not acceptable, round the number of treatments upwards e.g., 1 1/2 treatments are equal to 2. Place the total number of treatments in item 52. In the unlabeled column, enter the number of hours for each treatment so that proper reimbursement can be made.

Extended peritoneal dialysis sessions of 30 hours or more, given once a week, in place of 2 or 3 sessions of shorter duration are billed and reimbursed as three treatments. Enter the number of hours for each session in this column. Enter the number of treatments in item 52.

Item 51. Revenue Code

Required. For each cost center for which a separate charge is billed, assign a revenue code. Enter the appropriate three-digit numeric revenue code on the adjacent line in column 51 to explain each charge in column 53. This data takes the place of fixed line item descriptions on the billing form.

Additionally, there is no fixed "Total" line in the charge area. Instead, enter revenue code "001" last in column 51. Thus, the adjacent charge entry in column 53 is the sum of charges billed. This is also the same line on which charges, if any, you sum in columns 54-56.

To assist in bill review, list revenue codes in ascending numeric sequence to the extent possible. To limit the number of line items on each bill, sum revenue codes at the "zero" level to the extent possible. Following are revenue codes that could be billed by ESRD facilities.

25X Pharmacy

Charges for medication produced, manufactured, packaged, controlled, assayed, dispensed and distributed under the direction of a licensed pharmacist.

Use this category only for nonroutine drugs and biologicals since routine drugs and biologicals are included in the composite rate under Method I and are part of home dialysis supplies under Method II. Under METHOD II, nonroutine drugs and biologicals may only be billed by an ESRD facility if they are administered in the facility by its staff. They must be documented for medical necessity. The administration of drugs and biologicals, both staff time and supplies are covered and billed as revenue code 259.

Subcategory	Standard Abbreviation
0 - General Classification	PHARMACY
1 - Generic Drugs	DRUGS/GENERIC
2 - Non-generic Durgs	DRUGS/NONGENERIC
4 - Blood Plasma	BLOOD/PLASMA
5 - Blood-Other Components	BLOOD/OTHER
8 - IV Solutions	IV SOLUTIONS
9 - Other Pharmacy	DRUGS/OTHER

27X Medical/Surgical Supplies

Charges for supply items required for patient care.

Rationale: Additional breakdowns are provided for items that facilities may wish to identify because of internal or third party payer requirements.

Subcategory	Standard Abbreviation
0 - General Classification	MED-SUR SUPPLIES
2 - Sterile Supply	STERILE SUPPLY
3 - Take Home Supplies	TAKEHOME SUPPLY
4 - Prosthetic Devices	PROSTHETIC DEV
7 - Oxygen-Take Home	02/TAKEHOME
9 - Other Devices	SUPPLY/OTHER

30X Laboratory

Charges for the performance of diagnostic laboratory tests.

Rationale: A breakdown of the major areas in the laboratory is provided in order to meet facility needs or third party billing requirements.

Subcategory	Standard Abbreviation
0 - General Classification	LABORATORY or (LAB)
1 - Chemistry	LAB/CHEMISTRY
2 - Immunology	LAB/IMMUNOLOGY
3 - Renal Patient (Home)	LAB/RENAL HOME
4 - Non-Routine Dialysis	LAB/NR DIALYSIS
5 - Hematology	LAB/HEMATOLOGY
6 - Bacteriology & Microbiology	LAB/BACT-MICRO
7 - Urology	LAB/UROLOGY
9 - Other Laboratory	LAB/OTHER

Notes

1. Independent facilities do not bill for nonroutine lab tests under METHOD I and do not bill for any lab tests (routine or nonroutine) under METHOD II.

2. No other (routine) lab charges are billable in connection with outpatient or home dialysis where composite rate is billed.

31X Laboratory Pathological

Charges for diagnostic laboratory tests on tissues and cultures.

Rationale: A breakdown of the major areas that facilities may wish to identify is provided.

Subcategory	Standard Abbreviation
0 - General Classification	PATHOLOGY LAB or (PATH LAB)
1 - Cytology	PATHOL/CYTOLOGY
2 - Histology	PATHOL/HYSTOL
4 - Biopsy	PATHOL/BIOPSY
9 - Other	PATHOL/OTHER

32X Radiology - Diagnostic

Charges for diagnostic radiology services provided for the examination and care of patients. Includes: taking, processing, examining and interpreting radiographs and fluorographs.

Rationale: A breakdown is provided of the major areas and procedures that individual facilities or third party payers may wish to identify.

Subcategory	Standard Abbreviation
0 - General Classification	DX X-RAY
4 - Chest X-Ray	DX X-RAY/CHEST
9 - Other	DX X-RAY/OTHER

38X Blood

Rationale: Charges for blood must be separately identified for private payer purposes.

Subcategory	Standard Abbreviation
0 - General Classification	BLOOD
1 - Packed Red Cells	BLOOD/PKD RED
2 - Whole Blood	BLOOD/WHOLE
3 - Blood Plasma	BLOOD/PLASMA
4 - Blood Platelets	BLOOD/PLATELETS
5 - Blood Leucocytes	BLOOD/LEUCOCYTES
6 - Blood - Other Components	BLOOD/OTHER COMP
7 - Blood - Other Derivatives (Cryoprecipitates)	BLOOD/ OTHER DER
9 - Other Blood (Describe)	BLOOD /OTHER

39X Blood Storage and Processing

Charges for the storage and processing of whole blood.

Subcategory	Standard Abbreviation
0 - General Classification	BLOOD/STOR-PROC
1 - Blood Administration	BLOOD/ADMIN.
9 - Other Blood Storage & Processing	BLOOD/OTHER STOR

73X EKG/ECG (Electrocardiogram)

Charges for operation of specialized equipment to record electromotive variations in action of the heart muscle on an electrocardiograph for diagnosis of heart ailments.

Subcategory	Standard Abbreviation
0 - General Classifications	EKG/ECG
1 - Holter Monitor	Holter Mont
9 - Other EKG/ECG	Other EKG-ECG

82X Hemodialysis - Outpatient or Home Dialysis

A waste removal process performed in an outpatient or home setting, necessary when the body's own kidneys have failed. Waste is removed directly from the blood.

Rationale: Detailed revenue coding is required; therefore, do not sum services at the zero level.

Subcategory	Standard Abbreviation
0-General Classification	HEMO/OP OR HOME
1-Hemodialysis/Composite	HEMO/OP/COMPOSITE
2-Home Supplies	HEMO/HOME/SUPPL
3-Home Equipment	HEMO/HOME/EQUIP
4-Maintenance/100%	HEMO/HOME/100%
5-Support Services	HEMO/HOME/SUPSERV
9-Other Hemodialysis Outpatient	HEMO/HOME/OTHER

NOTE: Do not use the revenue code to indicate sessions under METHOD II. However, backup dialysis furnished to home patients in the facility may be billed. (See condition code 76.)

83X Peritoneal dialysis - Outpatient or Home

A waste removal process performed in an outpatient or home setting, necessary when the body's own kidneys have failed. Waste is removed indirectly by flushing a special solution between the abdominal covering and the tissue.

Subcategory	Standard Abbreviation
0-General Classification	PERITONEAL/OP OR HOME
1-Peritoneal/Composite	PERTNL/OP/COMPOSITE

2-Home Supplies	PERTNL/HOME/SUPPL
3-Home Equipment	PERTNL/HOME/EQUIP
4-Maintenance/100%	PERTNL/HOME/100%
5-Support Services	PERTNL/HOME/SUPSERV
9-Other Peritoneal Dialysis	PERTNL/HOME/OTHER

NOTE: Do not use the revenue code to indicate sessions under METHOD II. However, backup dialysis furnished to home patients in the facility may be billed. (See condition code 76.)

84X Continuous Ambulatory Peritoneal Dialysis (CAPD) - Outpatient
A continuous dialysis process performed in an outpatient or home setting, using the patient's peritoneal membrane as a dialyzer.

Subcategory	Standard Abbreviation
0-General Classification	CAPD/OP OR HOME
1-CAPD/Composite	CAPD/OP/COMPOSITE
2-Home Supplies	CAPD/HOME/SUPPL
5-Support Services	CAPD/HOME/SUPSERV
9-Other CAPD Dialysis	CAPD/HOME/OTHER

NOTE: Do not use the revenue code to indicate sessions under METHOD II. However, backup dialysis furnished to home patients in the facility may be billed. (See condition code 76.)

85X Continuous Cycling Peritoneal Dialysis (CCPD) - Outpatient
A continuous dialysis process performed in an outpatient or home setting, using the patient's peritoneal membrane as a dialyzer.

Subcategory	Standard Abbreviation
0-General Classification	CCPD/OP OR HOME
1-CCPD/Composite	CCPD/OP/COMPOSITE
2-Home Supplies	CCPD/HOME/SUPPL
3-Home Equipment	CCPD/HOME/EQUIP
4-Maintenance/100%	CCPD/HOME/100%
5-Support Services	CCPD/HOME/SUPSERV
9-Other CCPD Dialysis	CCPD/HOME/OTHER

NOTE: Do not use the revenue code to indicate sessions under Method II. However, backup dialysis furnished to home patients in the facility may be billed. (See condition code 76.)

86X Reserved

87X Reserved

88X Miscellaneous Dialysis

0 - General
1 - Ultrafiltration

Item 52. Units of Service
Required. The entries in this column quantify services by revenue category, e.g., number of dialysis treatments. Units are defined as follows:

82X(Hemodialysis) - Sessions
83X(Peritoneal) - Sessions
84X(CAPD) - Days covered by bill
85X(CCPD) - Days covered by bill

Item 53. Total Charges
Required. Show your customary charge in this item to correspond to the appropriate revenue code in item 51. Do not enter your composite rate as your charge. Sum the total charges for the billing period by revenue code (column 51) and enter on the adjacent line in column 53. The last revenue code entered in column 51 is "001" representing the total of all charges billed. Column 53 totals on the adjacent line. Each line allows up to eight numeric digits (000000.00).

Items 54, 55, and 56. Unlabeled Charge Column
Not required.

Items 57 A, B, C. Payer Identification
Required. If Medicare is the primary payer, enter "Medicare" on line A. When Medicare is entered on line 57A, this indicates that you have developed for other insurance and have determined that Medicare is the primary payer. All additional entries across line A (items 58-64) supply information needed by the payer named in item 57A. If Medicare is the secondary or tertiary payer, identify the primary payer on line A and enter Medicare information on line B or C as appropriate.

Items 58 A, B, C. Release of Information Certification Indicator
Not required. NOTE: The back of the UB-82 contains a certification by you that all necessary release statements are on file.

Items 59 A, B, C. Assignment of Benefits Certification Indicator
Not required.

Items 60 A, B, C. Deductible
Required. Enter the Medicare Part B cash and blood deductible amounts collected from the patient.

Items 61 A, B, C. Coinsurance
Required. Enter the Part B coinsurance collected from the patient.

Items 62 A, B, C. Estimated Responsibility
Not required.

Items 63 A, B, C. Prior Payments
Not required.

Item 64 A, B, C.
Not required.

Due From Patient (Unnumbered line below 57-64C)
Not required.

Item 65 A, B, C. Insured's Name
Required. On the same lettered line (A, B, or C) corresponding to the line on which Medicare payer information is shown in item 57-63, enter the patient's name as shown on the HI card or other Medicare notice.

If there are payer(s) of higher priority than Medicare and you are requesting payment because another payer paid some of the charges and Medicare is secondarily liable for the remainder, or you are requesting a conditional payment as described in §323D, enter the name of the individual in whose name the insurance is carried. If that person is the patient, enter "Patient." Payers of higher priority than Medicare include:

1. EGHPs for beneficiaries entitled to benefits solely on the basis of ESRD during a period of up to 12 months (see §250);

2. An auto-medical, no fault or liability insurer; or

3. A WC insurer (including BL).

Items 66 A, B, C. Insured's Sex
If claiming payment under any of the circumstances described under items 65 A, B, or C, enter the sex of the insured. Use the following codes:

M = Male
F = Female

Items 67 A, B, C. Patient's Relationship to Insured
If claiming payment under any of the circumstances described in items 65 A, B or C, enter the code indicating the relationship of the patient to the identified insured, if this information is readily available.

Code	Title	Definition
01	Patient is Insured	Self-explanatory
02	Spouse	Self-explanatory
03	Natural Child/Insured Financial Responsibility	Self-explanatory

04	Natural Child/Insured Does Not Have Financial Responsibility	Self-explanatory
05	Step Child	Self-explanatory
06	Foster Child	Self-explanatory
08	Employee	Patient is employed by the insured.
09	Unknown	Patient's relationship to the insured is unknown.
15	Insured Plaintiff	Patient is claiming insurance as a result of injury covered by insured.

Items 68 A, B, C. Certificate/Social Security Number/Health Insurance Claim/Identification Number

On the same lettered line (A, B, or C) that corresponds to the line on which Medicare payer information is shown in items 57-63, enter the patient's Medicare HICN, i.e., if Medicare is the primary payer, enter this information in item 68A. Show the number as it appears on the patient's HI Card, Certificate of Award, Utilization Notice, EOMB, Temporary Eligibility Notice, or as reported by the Social Security Office.

If you request any insurance coverage higher in priority than Medicare (e.g., employer coverage for the patient or his spouse age 65 to 69 or during the first year of ESRD entitlement), show the involved claim number for that coverage on the appropriate line.

Item 69 A, B, C. Group Name

Where claiming a payment under the circumstances described in items 65 A, B, or C and there is involvement of an EGHP or WC, enter the name of the group or plan through which that insurance is provided.

Item 70 A, B, C. Insurance Group Number

Where claiming a payment under the circumstances described in items 69 A, B, or C and there is involvement of an EGHP or WC, enter the identification number, control number or code assigned by that health insurance carrier to identify the group under which the insured individual is covered.

GUIDELINES FOR EMPLOYMENT INFORMATION

The following items are grouped for ease in transmitting instructions on their completion: 71, 72, 73, 74, 75. Space is reserved for reporting the necessary employment data for up to two individuals. Use the following sequence of decision making in completing these fields.

INDIVIDUAL CLAIMING INSURANCE

1. If any insured's named under A, B, or C in the insurance section of the form (item 65) has group insurance provided by an organization other than the employer, enter the insured's employment information and the EID (item 71) coded A, B, or C depending on the payer line the individual's insurance information is recorded. (For example, item 69 records Group Name as Washington Area Ford Dealers, Inc. but the insured's employer is Capital Ford, Inc. Since the insurance is held with a company other than the employer, the employer information is required for the insured.)

2. If any of the individuals recorded under A, B, or C in this insurance section of the form (item 65) has group insurance coverage provided by an employer who operates from multiple locations, enter employment information (and location) and the EID (item 71) coded A, B, or C depending upon the payer line the individual insurance information is recorded.

Item 71. Employment Information Data
Where claiming a payment under the circumstances described in items 69 A, B, or C and there is involvement of an EGHP or WC, enter the code that indicates whether the employment information given on the same line in items 72-75 applies to the insured, the patient or the patient's spouse.

Code Structure

A = Employment Information relates to primary insured
B = Employment Information relates to secondary insured
C = Employment Information relates to tertiary insured
P = Patient Employment Information
S = Spouse Employment Information
F = Father's Employment Information
M = Mother's Employment Information

NOTE: Where there is a single employer, enter only one code from the code structure.

When the employment information pertains to multiple payers from item 57, enter two codes from the code structure.

Item 72. Employment Status Code
Where claiming a payment under the circumstances described under items 69 A, B, or C and there is involvement of an EGHP or WC, enter the code which defines the employment status of the individual identified on the same line in item 71, if the information is readily available.

Code	Title	Definition
1	Employed Full Time	Individual stated that he or she is employed full time.
2	Employed Part Time	Individual stated that he or she is employed part time.

Item 73. Employer's Name
Where claiming a payment under the circumstances described in items 69 A, B, or C and there is involvement of an EGHP or WC, enter the name of the employer that provides health care coverage for the individual identified on the same line in item 71.

Item 74. Employee Identification Number
Where claiming a payment under the circumstances described in items 69 A, B, or C and there is involvement of an EGHP or WC, enter the identification number assigned by the employer to the individual identified on the same line in item 71.

Item 75. Employer Location
Where claiming a payment under the circumstances described in items 69 A, B, or C and there is involvement of an EGHP or WC, enter the specific location of the employer of the individual identified on the same line in item 71, city, plant, etc. in which the employer is located.

Item 76. Principal and Other Diagnoses Descriptions
Not required.

Items 85-93
Not required.

Item 94. Remarks

Enter special annotations where Medicare is not the primary payer because an EGHP is primary to Medicare (See §323 for appropriate annotations.) In addition, enter any other remarks needed to provide information that is not shown elsewhere on the bill but which is necessary for proper payment.

Enter the first month of the 12 month period during which Medicare benefits are secondary to benefits payable under an EGHP. (See occurrence code 33.)

321. COMPLETION OF FORM HCFA-1450, BY INDEPENDENT FACILITIES FOR HOME DIALYSIS ITEMS AND SERVICES BILLED UNDER DIRECT DEALING (METHOD II)

These instructions apply to home dialysis items and services billed and reimbursed under Method II. Under Method II all home dialysis items and services (including routine ESRD laboratory tests and routine parenteral items) are billed and reimbursed on an itemized basis.

The home dialysis patient may choose to obtain home dialysis equipment and/or supplies directly from a supplier that is not a facility. The patient (or supplier) bills the carrier. However, if the home dialysis patient chooses to obtain home dialysis equipment and/or supplies from the facility, the facility bills its intermediary on an itemized basis using a HCFA-1450.

There is no choice with respect to home dialysis support services. Only a dialysis facility may furnish, bill for, and be reimbursed for these services.

Complete all items on the HCFA-1450 in accordance with §320 except for the changes annotated for METHOD II billings under the revenue code description in Item 50.

Billing in Situations Where Medicare is Secondary Payer

323. BILL PREPARATION WHERE MEDICARE BENEFITS ARE SECONDARY TO EMPLOYER GROUP HEALTH PLANS WHEN INDIVIDUALS ARE ENTITLED TO BENEFITS SOLELY ON THE BASIS OF ESRD

A. General.—Medicare benefits are secondary to benefits payable under an employer group health plan (EGHP) in the case of individuals who are entitled to benefits solely on the basis of end stage renal disease (ESRD), during a period of up to 12 months. This provision is effective for items and services furnished on or after October 1, 1981, to beneficiaries whose 12-month period began in or after October 1981. For an explanation of these provisions see §250.

Payment made by the ESRD-EGHP can be used to satisfy unmet deductibles and the individual's coinsurance. (See §250.13.)

The instructions apply to facilities billing under Method I. See §§318.B, 318.2, and 321 for facilities billing under Method II.

Where Medicare is the primary payer, show Medicare on line A of item 57. Where Medicare is secondary, show Medicare on line B. In addition, when you are billing Medicare because the ESRD-EGHP denied payment, enter occurrence code 24 (insurance denied) and the date of the denial in items 28-32 (occurrence codes). Enter the reason for the denial in remarks (item 94). Where Medicare is not primary payer because of coverage of an ESRD beneficiary by an EGHP, prepare the bill in accordance with the following.

B. Outpatient Bills - Full Payment by EGHP.—If an ESRD-EGHP payment for Medicare covered services (as determined by the formula in C2 below) equals or exceeds your charges for the dialysis services or the composite rate (without regard to deductible or coinsurance), or you accept, or are obligated to accept, the ESRD-EGHP payment as payment in full and you know the individual has met the deductible, do not submit a bill.

If billing for services separately from the composite rate; e.g., separately billable parenteral items, add the Medicare reasonable charge for the services to the composite rate. If the ESRD-EGHP payment equals or exceeds this amount and the individual has met the deductible, do not submit a bill. However, submit a bill to inform the intermediary of charges where the deductible may not be met. Although no payment can be made, the expenses can be applied to the beneficiary's deductible. Complete the bill in accordance with §320. In addition:

- Determine the charges as usual, including those covered by the ESRD-EGHP payment. Your intermediary will treat the charges shown in total charges as noncovered for reimbursement purposes, but will credit the deductible based upon the bill.
- Enter the amount paid by the ESRD-EGHP for Medicare covered services in items 46-49 (value codes).
- Enter occurrence code 33, and the first month of the 12-month period in items 28-32.
- Enter the statement "No Medicare Payment Due/Payment Accepted as Payment in Full" in item 94 (Remarks) when you accept or are obligated to accept the ESRD-EGHP payment as payment in full.

C. Outpatient Bills - Partial Payment by EGHP.--If an ESRD-EGHP payment for Medicare covered services (as determined by the formula in 2 below) is less than your charges for the dialysis services and the composite rate or the composite rate plus the Medicare reasonable charge for services billed separately from the composite rate (without regard to deductible or coinsurance) and you do not accept, and are not obligated to accept, the payment as payment in full, complete or bill in accordance with §320 with the following modifications:

Determining covered charges

Show in the covered charges column the Medicare covered charges including those covered by the ESRD-EGHP payment.

Determining the amount of the primary payer payment that applies to Medicare covered services.

Where you can determine the primary payer's allocation of its payment between covered and noncovered Medicare services, indicate the amount paid by the primay payer toward Medicare covered services in value codes (items 46-49). Where you cannot determine the services covered by the primary payment, apply a ratio of Medicare covered charges to total charges for the services to the primary payment amount to determine the portion attributable to Medicare covered services. Indicate this amount in value codes (items 46-49). You must be able to validate your ratio of covered and noncovered charges if requested.

EXAMPLE:

Total charges were $110. Medicare covered charges were $90. The ESRD-EGHP payment was $88. Since you cannot determine the allocation of the primary payer's payment, determine the allocation as follows:

$$\frac{\$\ 90}{\$110} \times \$88 = \$72$$

Show $72 in value codes (items 46-49).

Determining the amount of Medicare payment

The amount of Medicare payment is the lower of:

- The composite rate plus the reasonable charge for any items billed separately from the composite rate (without regard to deductible or coinsurance) minus the amount paid by the ESRD-EGHP for Medicare covered services;

or

- The composite rate plus the reasonable charge for any items billed separately from the composite rate (without regard to deductible or coinsurance) minus any applicable Medicare deductible or coinsurance amount.

That portion of the total charges equal to the ESRD-EGHP payment is credited toward any unmet deductible.

EXAMPLE 1:

An individual received 8 dialysis treatments for which a facility charged $160 per treatment for a total of $1,280. No part of the beneficiary's $75 Part B deductible had been met previously. The ESRD-EGHP paid $1,024 for Medicare covered services. The composite rate per dialysis treatment is $131 or $1,048 for 8 treatments. As secondary payer, Medicare pays the lower of:

o The composite rate (without regard to deductible or coinsurance) minus the EGHP payment: $1,048-$1,024 = $24.

or

o The composite rate (without regard to deductible or coinsurance) minus the applicable deductible and coinsurance: $1,048-$75-$194.60* = $778.40.

*Calculate the coinsurance as follows:

$1,048 composite rate - $75 deductible = $973 x 20 percent = $194.60.

Medicare pays $24. You may not charge the beneficiary since the deductible and coinsurance were met by the ESRD-EGHP payment.

EXAMPLE 2:

An individual received 12 peritoneal dialysis treatments over a 1 month period for which an independent facility charged $150 per treatment. The facility billed on a monthly basis and its per treatment composite rate was $130 or $1,560 for the 12 treatments. The facility also billed the individual separately billable parenteral items for which it charged $45. The Medicare reasonable charge for these services was $36. The beneficiary's $75 Part B deductible was previously met. The ESRD-EGHP paid 80 percent of the facility's charges, or $1,476 for Medicare covered services. As secondary payer, Medicare pays the lower of:

o The composite rate plus the Medicare reasonable charge for the separately billable items (without regard to deductible or coinsurance) minus the ESRD-EGHP payment: $1,560 + $36 = $1,596 - $1,476 = $120.

or

o The composite rate plus the Medicare reasonable charge for the separately billable items (without regard to deductible or coinsurance) minus the applicable coinsurance: $1,560 + $36 - $319.20* = $1,276.80.

*Calculate the coinsurance as follows:

$1,596 x 20 percent = $319.20

Medicare pays $120. You may not charge the beneficiary since the coinsurance was met by the ESRD-EGHP payment.

Medicare pays $120. You may not charge the beneficiary since the coinsurance was met by the ESRD-EGHP payment.

Show the identifying information in Items 57-75 on the first payer line, value code 13 with the amount paid in value codes (Items 46-49) and occurrence code 33 and the first month of the 12 month period in Items 28-32 or the first month of the 12 month period in Remarks (Item 94). Enter the address of the ESRD-EGHP in Item 34 or Remarks (Item 94).

D. ESRD-EGHP Denies Claim for Primary Benefits.--Primary Medicare benefits may be paid (if the beneficiary is not appealing the ESRD-EGHP denial) when an ESRD-EGHP denies a claim for primary benefits because:

- o The beneficiary is not in a 12-month coordination period as defined in §§250.4 and 250.5;
- o The beneficiary is not entitled to benefits under the plan;
- o Benefits under the ESRD-EGHP are exhausted for the services involved; or
- o The services are not covered by the ESRD-EGHP.

Where the ESRD-EGHP denies payment for any of the reasons listed above, enter occurrence code 24 (insurance denied) and the date of denial in Items 28-32 (occurrence codes). In addition, provide a reason for the denial in Remarks (Item 94). Your intermediary will process the claim.

If an ESRD-EGHP denies a claim for primary benefits because the plan offers only secondary coverage of services covered by Medicare, Medicare benefits may not be paid (primary or conditional). Enter occurrence code 24 (insurance denied) and the date of denial in Items 28-32 (occurrence codes). In addition, enter the annotation "Plan offers only secondary coverage of services covered by Medicare" in Remarks (Item 94).

E. Conditional Payments.--If the beneficiary has appealed, or is protesting the ESRD-EGHP denial of the claim for any reason other than that the ESRD-EGHP offers only secondary coverage of services covered by Medicare or it denied the claim because the time limit for filing the claim with the ESRD-EGHP has expired (whether appealed or not) conditional primary Medicare benefits may be paid.

Request conditional payment by entering value code 13 with zero value in Items 46-49 to indicate the type of other insurer and that conditional payment is requested and occurrence code 24 (insurance denied) and the date of denial in Items 28-32 (occurrence codes). Enter the identity of the ESRD-EGHP on line A of Item 57, any identifying information about the insured on line A of Items 65-75, and the address of the ESRD-EGHP in Item 34 or Remarks (Item 94). In addition, enter the annotation "Beneficiary has appealed or is protesting ESRD-EGHP denial" or "Time limit for filing the claim with the ESRD-EGHP has expired" as appropriate in Remarks (Item 94).

Refunds

324. REFUND OF MONIES INCORRECTLY COLLECTED

Renal dialysis facilities bill Medicare for dialysis treatments, except for the deductible and coinsurance. Bill the Medicare patient directly only for the Part B deductible and coinsurance. Furthermore, coinsurance billed to the patient for covered dialysis services must be based on the charge determined by Medicare to be the reasonable charge. Coinsurance amounts along with Medicare payment for the covered dialysis service must not exceed what has been determined to be the facility's reasonable charge. (See §318 (15I) for a discussion of Medicare reimbursement amounts and how they are determined.)

Amounts incorrectly collected and not refunded represent improper charges for covered services. Money incorrectly collected are amounts in excess of allowable charges and deductible and coinsurance amounts, if applicable, paid to a facility by an individual (or other person on his behalf) as payment for covered items and services for which the individual is entitled to have payment made under the health insurance program. A majority of incorrect collections are made inadvertently and may involve a simple error on the part of the facility in billing a beneficiary. However, there are other situations which lend themselves to the possibility of an incorrect collection. Shown below are some examples:

1. In a retroactive entitlement case, where the beneficiary (or other person) paid for covered services and later becomes entitled to have payment made for them by Medicare;

2. Where an intermediary (carrier) has initially denied payment and a subsequent finding is made (e.g., as the result of a reconsideration or hearing decision) that payment for all or part of the services may be made;

3. Where the beneficiary or other person has protested a direct charge by a facility and the intermediary determines that the beneficiary is entitled to have program payment made on his behalf for all or part of the services.

The intermediary ensures that facilities refund monies incorrectly collected. Therefore, in the situations described above (and other similar situations recognized by the intermediary), the intermediary (carrier) determines, on an individual case basis, whether the facility has already received reimbursement for covered services from the individual or other person (e.g., relatives, other insurance carriers, or welfare) before making Medicare payment. If the facility advises, in writing, that it has not been reimbursed by the individual or other person for covered services, payment can be made. (See §324.1 for proper disposition and §324.2 for time limit within which refund or other disposition is to be accomplished.)

Where the intermediary knows that a facility has overcollected deductible and coinsurance amounts, direct refund is made by the intermediary to the beneficiary.

324.1 Return or Other Disposition of Monies Incorrectly Collected.--A facility in possession of any incorrect collection is required to refund or make final disposition of the money in accordance with applicable State law. If refund or final disposition will be delayed for a prolonged period, the facility is required to set aside the money in a

separate account until refund or final disposition can be made. Until the facility advises, in writing, that it has properly refunded or disposed of the money or, as necessary, set aside the money, the intermediary will withhold an amount equal to such incorrect collection against amounts otherwise due.

A. Refund.—Refund is to be made to the beneficiary (or any other person) from whom the facility collected the monies. If the beneficiary or other person cannot be located after the facility has made a reasonable effort (including contact by mail at the last known address), ask the intermediary to check HCFA's records. If the individual to whom refund is to be made still cannot be located or has died, make final disposition of the monies in accordance with State law.

B. Monies Set Aside.—In some situations refund or final disposition may be delayed for a prolonged period (e.g., where the beneficiary's whereabouts is being developed or where there is a delay in the appointment of a legal representative to dispose of the estate of a deceased individual). When such a delay in making refund or final disposition is encountered, notify the intermediary and set the funds aside in a separate account identified by the name of the individual to whom the payment is due. Carry these amounts on the records until refund or final disposition, as provided in A above, is made.

324.2 Appropriate Time Limits Within Which Facility Must Dispose of Sums Incorrectly Collected.—Refund or final disposition in accordance with applicable State law of sums incorrectly collected should be accomplished promptly. In any event, the refund, final disposition, or, as necessary, setting funds aside in a separate account, should be accomplished within a period of 60 days after notification of incorrect collection.

324.3 Former Facility.--Once a facility is in the Medicare program, it remains responsible, notwithstanding subsequent withdrawal of program approval or voluntary participation, for the required refund or final disposition of any monies incorrectly collected for covered services furnished to Medicare beneficiaries during the effective period of its program participation.

Protests and Appeals

326. FACILITY PROTESTS OF PAYMENT DETERMINATION

The facility and its intermediary should attempt to mutually resolve any differences involving payment for services.

328. BENEFICIARY APPEALS (PART B)

A. Beneficiary Appeal Rights.—An individual dissatisfied with the denial of a request for payment of Part B benefits or the amount of such benefits paid is entitled to a review by the intermediary. If dissatisfied with the promptness with which his initial request for payment is acted upon or with the outcome of the review determination, he is entitled to a hearing by the intermediary's hearing officer. However, a claimant's right to a Part B fair hearing is dependent upon a showing that there is $100 or more in controversy.

A similar appeals procedure applies to bills submitted to a carrier. Medicare beneficiaries, physicians, suppliers, and others who submit bills using Form HCFA-1500 shoud contact the carrier when there is a disagreement.

Medicare sends a notice to the claimant informing him of the steps he can take in requesting an appeal. If more information is needed about a cliamant's right or appeal, advise him to call or visit the nearest SSO.

B. Handling Beneficiary Protests.—Refer patient protests concerning entitlement to Part B benefits, e.g., enrollment, premium payment to the SSO. Handle protests concerning the denial, amount, or promptness of payment for items or services furnished by you that are amendable to explanation or correction. If the beneficiary is still dissatisfied, refer him to a SSO, which can assist the beneficiary in determining his appeal rights and can answer specific questions about the appeal procedures. it can also assist the individual in completing the necessary forms for requesting a reconsideration or hearing.

330. REOPENING AND REVISION OF MEDICARE CLAIMS DECISION

An initial or revised determination on a Part A or Part B Medicare claim may be reopened for any reason (and revised if found to be incorrect) within 1 year after the date of the decision.

After 1 year but within 4 years after the date of the initial decision, a determinaition may be reopened for "good cause," i.e., because:

- o New and material evidence is furnished;
- o A clerical error had been made; or
- o There is an error on the face of the evidence; on the basis of all of the evidence on file at the time the decision was made, it is clear that the decision was incorrect.

A determination may be reopened at any time if the decision was procured by fraud or similar fault. Correction of a clerical error or an error on the face of the evidence that would make the decision more favorable to the claimant can also be made at any time.

Retention of Records

332. RETENTION OF HEALTH INSURANCE RECORDS

Maintain health insurance material related to services rendered under Medicare for the prescribed retention periods outlined below unless State law stipulates a longer period of retention. They must made available to HCFA, the intermediary, DHHS Audit Agency, or other designated components for bill review, audit, and other references during the retention period.

A nonhospital renal dialysis facility may microfilm all health insurance records. Such records include your dialysis or home dialysis supply and equipment claims, your copies of form HCFA-1450, supporting documents and forms, charge slips, and other business and accounting records referred to specific claims. Billing material with any attachments that you furnish to your intermediary may be destroyed, providing the microfilm accurately reproduces all original documents. Retain these for 3 years after the month the claims were submitted to the intermediary.

332.1 Destruction of Health Insurance Records.—When material need no longer be retained for Medicare purposes, it may be destroyed unless State law stipulates a longer period of retention.

To insure the confidentiality of the records, it is requested that they be destroyed by shredding, mutilating, or using other protective measures. The method of final disposition of the records may provide for their sale as salvage. Report monies received as an adjustment to expense in the cost report for the year sold.

Claims Processing Timeliness Requirments

333. CLAIMS PROCESSING TIMELINESS

A. Claims Processing Timeliness Requirements.—"Clean" claims must be paid or denied within the applicable number of days from the date of their receipt as follows:

Time Period for Claims Received	Applicable Number of Days
02-01-86 thru 09-30-87	30
10-01-87 thru 09-30-88	26
10-01-88 thru 09-30-89	25
10-01-89 and later	24

NOTE: For interest payments the time period begins 04-01-87.

See subsection D for the definition of a clean claim. All claims (i.e., paid claims, partial and complete denials, no payment bills), including EMCs are subject to the above requirements.

The count is started on the day after the receipt date and ends on the date payment is made. For example, for claims received October 1, 1987 through September 30, 1988, if this span is 26 days or less the requirement is met.

B. Payment Floor Standards.—Your intermediary will not pay, issue, mail, or otherwise reimburse for any claim it receives from you within the waiting period indicated below. The length of the waiting period is determined by the date a claim is received. Your intermediary starts its count on the day after the day of receipt. For example, a claim received July 1, 1988 can be paid on or after July 12, 1988.

Claims Receipt Date	Waiting Period (Calendar Days)
07-01-88 thru 09-30-88	10
10-01-88 thru 09-30-89	14

NOTE: No payment claims are not subject to the payment floor standards.

C. Interest Payment on Clean Claims Not Paid Timely.--Interest must be paid on clean claims if payment is not made within the applicable number of calendar days after the date of receipt as described in subsection A. For example, a claim received on October 1, 1987, must have been paid before the end of business on October 27, 1987. Interest is not paid on:

- o Claims requiring external investigation or development by your intermediary;
- o Claims on which no payment is due; or
- o Full denials.

Interest is paid on a per bill basis at the time of payment.

Interest is paid at the rate used for §3902(a) of title 31, U.S. Code (relating to interest penalities for failure to make prompt payments). The interest rate is determined by the applicable rate on the day of payment.

This rate is determined by the Tresury Department on a 6 month basis. Interest is calculated using the following formula:

Reimbursement amount x rate x days divided by 365 = interest payment.

The interest period begins on the day after payment is due and ends on the day of payment.

EXAMPLE: Date received - January 1, 1989
Payment due - on January 26, 1989
Payment made - February 09, 1989
Interest begins - on January 27, 1989
Interest ends - February 09, 1989
Days for which interest due - 14 days
Amount of reimbursement = $100
Annual interest rate = 9.75%

The formula is applied as follows:

$100 x .0975 x 14 divided by 365 = $.373 or $.37 when rounded to the nearest penny.

When interest payments are applicable, your intermediary indicates for the individual claim the amount of interest on its remittance record to you.

D. Definition of "Clean Claim".--A "clean" claim is one which:

o Your intermediary does not investigate or develop external to its operation on a prepayment basis; and

o Your intermediary receives a definitive query response within 7 days of its original query. A definitive query response is one which provides your intermediary with all the eligibility data needed to process the claim.

Examples are claims which:

o Pass all edits and are processed electronically;

o Are investigated within your intermediary's claims, medical review, or reimbursement office without the need to contact you, the beneficiary, or SSA;

o Are subject to MR but complete medical evidence is attached by you or forwarded simultaneously with EMC records in accordance with your intermediary's instructions. If medical evidence must be requested, see first item under subsection E; or

o Are developed on a postpayment basis.

E. Other Claims.—Claims which do not meet the definition of "clean" are considered "other" claims. These include those which require investigation or development external to your intermediary's operation on a prepayment basis. In addition, if your intermediary does not receive a definitive query response within 7 days of its original query, the claim is considered an "other" claim regardless of whether it develops externally. Examples are claims on which your intermediary:

o Requests additional information from you or another source. This includes routine data omitted from the bill, medical information, or information to resolve discrepancies;

o Requests information or assistance from another contractor, e.g., development data obtained through the carrier-intermediary data exchange;

o Develops MSP information;

o Requests information necessary for a coverage determination;

o Performs sequential processing when an earlier claim is in development;

o Requeries because an original query has not been answered within 7 days; or

o Does not receive a definitive query response within 7 days of its original query date.

NOTE: If your intermediary is a Common Working File dependent intermediary, a claim is considered "other" if your intermediary continues to receive notification of claim recycling.

399. EXHIBITS

Exhibit 1. Health Insurance Cards

Exhibit 2. Social Security Award Certificate, SSA-30

Exhibit 3. Social Security Award Notice, SSA-30(BD)

Exhibit 4. Temporary Notice of Eligibility

Exhibit 5. Social Security Health Insurance Certificate, SSA-31

Exhibit 6. State Abbreviation Codes

EXHIBIT 2

Social Security Award Certificate

Department of Health, Education, and Welfare
Social Security Administration

Date

Name and Address of Payee as the Claimant
Or as Representative of the Claimant

Claim Number

Type of Benefit	Date of Entitlement	Monthly Benefit

Amount of First Payment:

This certifies that you (or the person(s) on whose behalf you applied), became entitled under the Social Security Act to the social security benefits shown.

James B Cardwell
Commissioner of Social Security

SSA-30 (3-76) **Important: See other side for information about your rights and responsibilities ▶**

Rev. 2

3-45

If you believe this determination is not correct, you may request that your claim be re-examined. If you want this reconsideration you must request it not later than 60 days from the date you receive this notice. You may make your request through any social security office. If additional evidence is available, you should submit it with your request.

The right to receive social security benefits carries with it certain responsibilities. They are explained in the booklet furnished you. Read this booklet carefully. Be sure that you understand clearly what you can expect by way of benefits, and what is to be expected of you. If you have any questions or wish additional information about your benefits, please get in touch with any social security office. Most questions can be handled by telephone or mail. If you visit an office, however, please take this Certificate with you.

KEEP AS A PERMANENT RECORD — DO NOT DESTROY

EXHIBIT 3

Social Security Award Notice

This is a notice that the person(s) named below will become entitled to the insurance benefits shown payable under Title II of the Social Security Act, if and when the disability impairment of the insured person has continued for at least five consecutive calendar months and provided he meets all other statutory requirements.

Department of Health, Education, and Welfare
Social Security Administration

Date

Name and Address of Payee as the Claimant
Or as Representative of the Claimant

Claim Number

Type of Benefit	Date of Entitlement	Monthly Benefit

Amount of First Payment:

Your first check should be received early in the month following the date of entitlement shown above unless your condition improves or you return to work before that month. Although the evidence shows that you are disabled, the law requires that your disability must exist for at least 5 full calendar months before you can qualify for disability insurance benefits.

JAMES B. CARDWELL
COMMISSIONER OF SOCIAL SECURITY

SSA-30(3-76)BDI. IMPORTANT: See other side for information about your rights and responsibilities ▶

Rev. 2

3-47

If you believe this determination is not correct, you may request that your claim be re-examined. If you want this reconsideration you must request it not later than 60 days from the date you receive this notice. You may make your request through any social security office. If additional evidence is available, you should submit it with your request.

The right to receive social security benefits carries with it certain responsibilities. They are explained in the booklet furnished you. Read this booklet carefully. Be sure that you understand clearly what you expect by way of benefits, and what is to be expected of you. It is also most important that you report promptly if any of these events occur before the month your benefits begin since any change in your status could affect the determination. If you have any questions or wish additional information about your benefits, please get in touch with any social security office. Most questions can be handled by telephone or mail. If you visit an office, however, please take this notice with you.

KEEP AS A PERMANENT RECORD--DO NOT DESTROY

EXHIBIT 4

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
SOCIAL SECURITY ADMINISTRATION
BALTIMORE, MARYLAND 21241

District Office Address:

Date:

Patient's Health Insurance
Claim Number

Dear

Based on the information given to the Social Security Administration regarding your chronic renal condition, you are eligible for hospital insurance beginning and for medical insurance beginning This notice will serve as evidence of your eligibility for these benefits for 60 days from the date shown at the top of this notice. Within 60 days you may expect to receive a health insurance card which you should show to hospital authorities or your physician whenever medical services are needed.

To obtain medical services (or reimbursement for medical services) before you receive your health insurance card, show this letter to your hospital or doctor but keep the letter with you. All bills or correspondence should show your health insurance claim number as shown above.

This temporary notice of eligibility is to be used only by the person to whom it is addressed and should be destroyed as soon as the health insurance card is received. Misuse is unlawful and will make the offender liable to a penalty.

If you have any questions, please contact the people at any social security office.

Sincerely yours,

James B. Cardwell
Commissioner of Social Security

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Rev. 2

EXHIBIT 5

Social Security
Health Insurance Certificate

Department of Health, Education, and Welfare
Social Security Administration

Date

Name and Address of the Claimant
or Representative of the Claimant

Claim Number

Date of Entitlement

Type of Coverage

This certifies that you (or the person(s) on whose behalf you applied) is entitled on the date indicated to the insurance benefits shown under Title XVIII of the Social Security Act.

IMPORTANT: See other side for information about your rights and responsibilities ▶

James B. Cardwell
Commissioner of Social Security

Form SSA-31 (9-76) **KEEP AS A PERMANENT RECORD—DO NOT DESTROY**

3-50

Rev. 2

KEEP THIS NOTICE AS A PERMANENT RECORD

General Information

HOSPITAL INSURANCE will pay most hospital bills and certain post-hospital expenses, while MEDICAL INSURANCE will help pay much of the medical expenses incurred for physicians and other medical services. The front of this notice shows whether you are entitled to HOSPITAL INSURANCE only, MEDICAL INSURANCE only, or both HOSPITAL and MEDICAL INSURANCE. Benefits are payable if covered services were rendered on or after the entitlement date shown. You will receive by mail a health insurance card and booklet explaining how to use the card, the services that are covered, and the methods of claiming benefits for covered services. If you are planning changes in any other hospital or medical insurance you now have, remember that Social Security Health Insurance coverage will be effective with the dates shown on the front of this notice.

If you need Medicare services before you receive your health insurance card, you may use this notice as proof of coverage.

If you need help with medical expenses before your health insurance coverage begins, or if you need aid in meeting medical expenses not covered by your health insurance, you may want to get in touch with the nearest Social Services Office to see whether you are eligible under its programs of medical assistance.

CHANGE OF ADDRESS: Notify any Social Security Office IMMEDIATELY if you change your address so that your health insurance card and any claims or informational material may reach you promptly.

RECONSIDERATION: If you believe that this determination is not correct, you may request that your case be re-examined. If you want this reconsideration, you must request it not later than 60 days from the date you receive this notice. You may make any such request through any social security office.

CLAIM NUMBER: Always give your claim number (see other side) on any letter or notice you send about your claim.

If you have any questions about your claim, you should get in touch with any social security office. If you call in person, please take this notice with you.

EXHIBIT 6

STATE ABBREVIATION CODES

Alabama	AL	Kentucky	KY	North Dakota	ND
Alaska	AK	Louisiana	LA	Ohio	OH
Arizona	AZ	Massachusetts	MA	Oklahoma	OK
Arkansas	AR	Maine	ME	Oregon	OR
California	CA	Maryland	MD	Pennsylvania	PA
Colorado	CO	Michigan	MI	Rhode Island	RI
Connecticut	CT	Minnesota	MN	South Carolina	SC
Delaware	DE	Mississippi	MS		
District of Columbia	DC	Missouri	MO	South Dakota	SD
Florida	FL	Montana	MT	Tennessee	TN
Georgia	GA	Nebraska	NB	Texas	TX
Hawaii	HI	Nevada	NV	Utah	UT
Idaho	ID	New Hampshire	NH	Vermont	VT
Illinois	IL	New Jersey	NJ	Virginia	VA
Indiana	IN	New Mexico	NM	Washington	WA
Iowa	IA	New York	NY	West Virginia	WV
Kansas	KS	North Carolina	NC	Wisconsin	WI
				Wyoming	WY

OUTLYING AREAS OF THE UNITED STATES

Canal Zone	CZ	Puerto Rico	PR
Guam	GU	Virgin Islands	VI

IM 300 Reduction in Medicare Program Reimbursement Due to P.L.99-177

A. General - P.L. 99-177 requires a reduction in all Medicare program payments. Special provisions limit the reduction in program reimbursement to 1 percent for the period March 1, 1986 through September 30, 1986.

The intermediary will reduce all Medicare program payments after applying deductible, coinsurance, and any applicable Medicare Secondary Payer (MSP) adjustment. It will reduce each claim or interim payment (including PIP).

B. Definitions.—

Date of Service: For all services, the intermediary will apply the reduction to all bills received with through dates on or after March 1. You may bill earlier services separately to avoid the reduction.

Affected Providers: All Medicare providers, both PPS and non-PPS, are affected.

Reduction Amount: The reduction amount for Medicare program payment is limited to 1 percent for FY 1986, beginning March 1, 1986, and 2 percent for each subsequent fiscal year. It may be less than the 1 percent or 2 percent limitation depending upon the amount of the Federal budget deficit. The actual amount of reduction is determined by February 1 for 1986 and by October 15 for each succeeding year, e.g., the October 1, 1986 payment reduction will be determined on October 15, 1986.

C. Changes Required in Bill Payment Procedures.—

For all services, you may bill separately for services prior to March 1, 1986, in order to avoid reduction of the entire bill.

The intermediary will reduce all bills with dates of service or through dates on or after March 1, 1986. It will not develop bills where the bill may contain earlier services, and will not accept adjustment bills to correct earlier bills spanning March 1. (See IM 86-1 in Part II of the Provider Reimbursement Manual for application of the reduction to your cost reports.)

You can expect reduction on final payments and interim payments (cost based interim payments). When payment is for laboratory services, the intermediary will make the reduction after it decides whether the charge or fee schedule is lower.

The intermediary will adjust payment amounts, not payment rates. It will apply the reduction to the amount that would have been paid before P.L. 99-177, i.e., after reduction for deductible, coinsurance, and MSP. Applying the 1 percent reduction after reduction for deductible, coinsurance, and MSP provides a slightly higher payment to you than applying the 1 percent reduction before deductible, coinsurance, and MSP.

You may not collect the reduction amount from beneficiaries.

IM 328 BENEFICIARY APPEALS (PART B)

A. General.--Section 9341 of the Omnibus Budget Reconciliation Act of 1986 (OBRA) (Public Law 99-509) provides for Administrative Law Judge (ALJ) hearings and judicial review for Part B claims denials, subject to minimum amounts in controversy. Section 9313(b) reaffirms the right of beneficiaries to appeal both Part A and Part B technical denials of home health benefits, e.g., denials for failure to meet the homebound or intermittent nursing care requirements.

B. Contractor Fair Hearing.--The contractor fair hearing is a prerequisite for an ALJ hearing. If less than $500 is in controversy following the contractor hearing officer's decision, no further appeals are available.

C. ALJ Hearings and Judicial Review for Part B Denials.--A person (including a provider or physician entitled to a hearing under §1879 of the Act) who is dissatisfied with the contractor hearing officer's decision on a Part B claim in which the amount remaining in controversy is at least $500, is entitled to a hearing before an ALJ. If at least $1,000 remains in controversy following the ALJ's decision, the claimant is entitled to judicial review before a Federal district court judge. This provision applies to items and services furnished on or after January 1, 1987.

D. Determining Amount in Controversy.--Section 9341 provides that in determining the amount in controversy, the Secretary, under regulations, shall allow two or more claims to be aggregated if they involve:

1. The delivery of similar or related services to the same individual, or

2. Common issues of law and fact arising from services furnished to two or more individuals.

Until new regulations are promulgated, follow the current rules for aggregating Part A and Part B claims. These rules are found in the regulations, for Part A, at 42 CFR §405.740 and, for Part B, at 42 CFR §405.820(b). The interim application of the pre-existing rules will not prejudice the rights of any claimant since the pre-existing rules respecting aggregation are less restrictive than the aggregation requirements of §9341.

E. Time Periods for Filing for Hearings.--Where Part B benefits are denied, the claimant has the right to a contractor hearing if at least $100 is in controversy and following that, an ALJ hearing, if at least $500 remains in controversy. (See B. and C. above.)

A contractor fair hearing (amount in dispute at least $100) must by regulation be requested within 6 months of the date of the review determination. An ALJ hearing (amount remaining in dispute after the contractor hearing at least $500) must by law be requested within 60 days of the date of receipt of the contractor hearing officer's decision.

F. Methods of Requesting Hearing.—The request for contractor fair hearing must be in writing and filed with the intermediary or a SSO. It may be any written expression of dissatisfaction with the intermediary review determination or a filing of Form HCFA-1965 -- "Request for Hearing — Part B Medicare Claim." The SSO forwards the request for hearing to the appropriate intermediary.

G. Action by Intermediary Upon Receipt of Request for Hearing.—When a request for contractor hearing is filed, the intermediary notifies the claimant or representative that the contractor hearing officer will be contacting him about the request. Then the intermediary forwards the case file to a hearing officer who will take one of two actions:

1. Dismiss the hearing request if the hearing officer believes there is under $100 in controversy; or

2. Process the hearing request if the hearing officer believes that the amount in controversy is at least $100.

H. Hearing Decision.—The hearing officer's decision should contain the following appeals right language depending on the amount of benefits in controversy:

1. Amount Remaining in Controversy Is At Least $500.--"On the basis of this decision, I have determined that there is $_____ in question. Therefore, you may request a hearing by an Administrative Law Judge (ALJ) if you do not agree with this decision. You must request the hearing within 60 days of the date of receipt of this letter.

Write to me or contact any social security office if you want a hearing. Your request will be sent to the ALJ. The ALJ will then advise you what you have to do to prepare for the hearing."

2. Amount in Controversy Below $500.--"On the basis of this decision, I have determined that there is $_____ in question. Therefore, there are no other levels of appeal available to you. However, if you think I have made a mistake you may ask me to open the case again. To do this you must write me as soon as possible. Include with your letter any additional information you may have which you feel may result in a more favorable decision."

I. Hearing Officer Action Upon Receipt of Request for ALJ Hearing.--When the contractor hearing officer, following his decision, receives a request for an ALJ hearing in which the amount remaining in controversy is at least $500, the hearing officer will take the following action:

1. New Evidence.—If any new evidence is submitted with the hearing request, the hearing officer reviews the case file to determine if the claim(s) may be reversed fully in favor of the claimant. If a full reversal is in order, the hearing officer prepares a decision containing the following elements:

- o A clear statement of the issues,
- o An explanation describing the reasons why a fully favorable decision is possible, with reference to the facts and evidence in the case,
- o A statement of the statutory or regulatory basis for the decision,
- o The decision, i.e., what the claimant can expect, and
- o Signature of the HO.

The hearing officer forwards the full reversal decision to the claimant; then, he forwards the case file to the intermediary for effectuation of the decision. (A full reversal decision is actually a reopening and revision of the hearing officer's decision.)

2. Case File to ALJ.—Unless the claim(s) warrants a full reversal, the hearing officer forwards the file to the ALJ. Prior to forwarding the file, he reviews it carefully to ensure that all available evidence is included. If a partial reversal appears possible, based on any new evidence submitted, he includes that in an explanation to the ALJ.

J. Limitation on Authority of ALJs and Courts.—Section 9341 of OBRA stipulates the following limitations on the authority of ALJs and the Courts to rule on appealed Medicare claims:

1. ALJs have no authority to overturn national coverage determinations made by HCFA under §1862(a)(1) of the Act, i.e., determinations that a particular category of items or services is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. However, the ALJ will determine whether the "limitation of liability" rules in 42 CFR 405.332 were applied correctly, i.e., whether the beneficiary or provider (or both) knew or could reasonably have been expected to know that the items or services were not covered. Although the substantive national coverage determination may not be overturned by an ALJ, it is subject to judicial review, as limited as provided in paragraph 2.

2. In judicial review of the ALJs' decisions, courts have no authority to overturn a national coverage determination made under §1862(a)(1) of the Act solely on the grounds that the coverage rule relied upon in making the determination was not issued in accordance with the notice and comment procedures of the Administrative Procedure Act. In any case in which a court determines that the record is incomplete or otherwise lacks adequate information to support the validity of the determination, it must remand the matter to the Secretary for additional proceedings to supplement the record. The court may not determine that an item or service is covered except upon review of the supplemented record.

3. Regulations and policy instructions initially issued prior to January 1, 1981 which concern a method for determining the amount of payment under Part B are not subject to judicial review.

402. REIMBURSEMENT FOR FACILITY DIALYSIS SERVICES

Subject to the deductible and coinsurance, the amount reimbursable to a non-hospital renal dialysis facility for a maintenance dialysis treatment or self-care dialysis session is computed by the intermediary as the lower of:

A. the customary charge of this facility for a dialysis treatment or self-care dialysis training session based on the weighted average of reimbursements from all parties made to the facility for such treatments furnished during the 12-month period preceding July 1, 1973.

If a customary charge cannot be derived on this basis because the facility was not in operation during the 12-month period preceding July 1, 1973, the facility's proposed schedule of charges and those of other facilities in the area will be considered in determining the reimbursable amount.

OR

B. the appropriate facility dialysis payment screens described in §402.2 below.

402.1 Exceptions to the Reimbursement Rate.--A facility which can demonstrate a need for a rate of reimbursement in excess of its current rate may submit documentation of its costs and request a reimbursement exception.

When a facility requests an exception, it must submit a statement explaining the reasons that may justify its excess costs. For example, a facility's costs may be higher than those ordinarily experienced because the facility retains in its renal dialysis program only those patients who require extraordinary care for specific medical reasons. Accordingly, more personnel time per patient is necessary. This may require the facility to retain a larger staff than may be needed by a facility that has patients requiring less individual care during the course of a dialysis treatment. Therefore, the cost per dialysis may be higher in this facility than in other facilities.

The facility sends this information to its intermediary who reviews it for completeness and accuracy. Once the intermediary determines that the request is complete, it makes a recommendation on the request and forwards it to HCFA's Central Office:

Health Care Financing Administration
Division of Alternative Reimbursement Systems
1-A-1 East Low Rise
6325 Security Boulevard
Baltimore, Maryland 21207

402.2 Facility Dialysis Payment Screens.--Reimbursement for facility dialysis services is limited by one of the payment screens listed below. The basic screens are $138 per treatment for maintenance dialysis and $158 per treatment for self-dialysis training. These amounts are modified under certain circumstances, as discussed below.

Summary of Facility Payment Screens

Treatment Condition	Physicians on Alternative Method(1)	Physicians Not on Alternative Method
Maintenance dialysis with routine laboratory(2)	138	150
Maintenance dialysis without routine laboratory(2)	133	145
Self-care dialysis training with routine laboratory	158	170
Self-care dialysis training without routine laboratory	153	165
Extended peritoneal dialysis (20-29 hours duration) with routine laboratory(3)	207	225
Extended peritoneal dialysis (20-29 hours duration) without routine laboratory(3)	199.50	217.50

(1)The alternative reimbursement method (ARM) for physician services is described in Section 901.3 of the Provider Reimbursement Manual, Part 2 (HCFA Pub. 15-2-8).

(2)These rates apply to maintenance hemodialysis and maintenance intermittent peritoneal dialysis but not continuous ambulatory peritoneal dialysis (CAPD). CAPD is a home dialysis maintenance therapy and not an infacility maintenance therapy.

(3)When extended peritoneal dialysis of 20-29 hours duration is needed more frequently than twice per week, additional medical evidence must be submitted to and accepted by the intermediary before additional payment can be made.

Treatment Condition	Physicians on Alternative Method[1]	Physicians Not on Alternative Method
Extended peritoneal dialysis (30 hours or more) with routine laboratory[4]	414	450
Extended peritoneal dialysis (30 hours or more) without routine laboratory[4]	399	435
Self-care intermittent peritoneal dialysis training with routine laboratory	158	170
Self-care intermittent peritoneal dialysis training without routine laboratory	153	165
Self-care continuous ambulatory peritoneal dialysis training with routine laboratory	150	162
Self-care continuous ambulatory peritoneal dialysis training without routine laboratory	145	157

(4) When extended peritoneal dialysis of 30 hours or more is needed more frequently than once per week, additional medical evidence must be submitted to and accepted by the intermediary before additional payment can be made.

*U.S. GOVERNMENT PRINTING OFFICE: 1989--241-194/05125